

**COST RECOVERY IMPLEMENTATION STATEMENT**

**Listing of medicines on the Pharmaceutical Benefits Scheme and designated vaccines on the National Immunisation Program**

**1 July 2023 to 30 June 2024**

**Version 1.8**

| Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a regulatory activity. This may include goods, services or regulation, or a combination of them. The Australian Government Charging Framework, which incorporates the Cost Recovery Guidelines (the CRGs)[[1]](#footnote-1), sets out the framework under which government entities design, implement and review regulatory charging activities, consistent with the *Public Governance, Performance and Accountability Act 2013*. |
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**1. INTRODUCTION**

1.1 Purpose of the Cost Recovery Implementation Statement (CRIS)

This CRIS provides information on how the Department of Health and Aged Care (the Department) implements cost recovery for:

* Submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) for medicines seeking to be listed on the Pharmaceutical Benefits Scheme (PBS); or vaccines to be listed on the National Immunisation Program (NIP).
* Applicant-driven PBS listing and list management activities.

This CRIS outlines the fees that apply for the 2023-24 financial year and the legislative changes to support more efficient administration of cost recovery arrangements. This CRIS also contains financial forecasts for the 2022-23 and 2023-24 financial years and three forward years and the financial and non-financial results for the 2021-22 financial year.

The Department will maintain and update the CRIS as required until the activity or cost recovery for the activity has been discontinued.

1.2 Description of the regulatory charging activity

**What is the regulatory activity being cost recovered?**

Cost recovery activities and fees associated with evaluation of submissions and the listing of medicines, vaccines and other products or services on the PBS and NIP commenced on 1 January 2010. In 2015, the Australian Government Charging Framework and the Cost Recovery Guidelines (the CRGs) were introduced.

During 2017 and 2018, the Department developed a revised cost model in alignment with the CRGs to ensure the model reflected the efficient costs of providing PBS/NIP evaluation and listing services to industry. The revised model also included the activities and costs associated with the first stage of PBS process improvements. This model and the revised cost recovery arrangements were approved by Government in the 2018-19 Mid-Year Financial Estimates Outlook and commenced on 1 July 2019.

To support implementation of the Stage 2 PBS process improvements, the Department further reviewed and updated the 2018-19 cost model in 2020. Additional activities were identified as part of revising submission categories and the new resubmission pathways. In addition, changes were made to all fees to reflect contemporary IT costs, depreciation, and salary and wage costs to meet whole-of-Government requirements. Stage 2 PBS process improvements were implemented on 1 January 2021 after the model and revised cost recovery arrangements were approved by Government in the 2020-21 Budget.

In line with the CRGs, cost recovery fees only recover the costs of those services directly requested by sponsors.

The cost recovered services for PBS/NIP evaluation, listing and management include:

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

ATAGI pre-submission advice

ATAGI advises the Minister for Health (the Minister) on the NIP and other immunisation issues. In 2006, amendments to the National Health Act 1953 were made to require a positive recommendation from the PBAC in order to list vaccines on the NIP. ATAGI has been providing pre‑submission advice to vaccine applicants and evaluation advice to the PBAC since that time.

Cost recoverable activities include ATAGI activity in providing advice to support the PBAC's evaluation of vaccines for the NIP, including on clinical, technical and implementation matters. Fees for this service were first introduced in mid-2020.

PBAC pre-submission meetings and Submission Services

The PBAC is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and consumer representatives. Its primary role is to recommend new medicines for listing on the PBS or NIP. No medicine can be listed (or have its listing amended) unless the PBAC makes a positive recommendation. PBAC has two sub-committees: the Drug Utilisation Sub Committee (DUSC) and the Economics Sub Committee (ESC) to assist with analysis and advice.

Cost recoverable activities include pre-submission advice provided by the Department to assist applicants in developing their PBAC submission and evaluation activity to support the PBAC's evaluation of medicines for listing on the PBS. Fees for pre-submission meetings were first introduced in mid-2019. Fees for evaluation activity and provision of advice to support the PBAC’s evaluation of medicines for listing on the PBS have been in place since 2010.

PBS Pricing Services (Pricing Pathways)

Pricing services include activities directly requested by applicants seeking to list on the PBS following a ‘recommended’ PBAC outcome. Pricing fees have been in place since 2010. Revised fees to support sponsor identified, individual listing requirements were first introduced in mid-2019. There are five pathways for finalising listing terms and conditions:

* Pricing Pathway A (only applies where nominated by the PBAC and accepted by an applicant);
* Pricing Pathway B (new deed);
* Pricing Pathway C (existing deed);
* Pricing Pathway D (no deed); and
* Pricing Secretariat.

PBS List Management Services

PBS list management includes activities that are directly requested by sponsors seeking to manage their medicine’s listing. Fees were first introduced in mid-2019 for price change requests. Deed-related fees were introduced on 1 January 2021. List management services include:

* Price increase requests including brand premium requests;
* Ministerial discretion requests;
* Deed renewal requests;
* Deed variation requests; and
* Ministerial determination requests (stockholding requests).

**What policy outcomes will the activity achieve?**

The activity for reviewing and approval of products for PBS/NIP listing and management is appropriate for cost recovery for the following reasons:

* It provides an important means of improving the efficiency and equity with which Government services are provided.
* Charging of fees sends price signals to individuals or groups about the cost or value of a government activity.
* The services are requested by an identifiable group of parties who cause regulatory effort for the listing of their products on the PBS or NIP.
* It ensures the quality use of PBS listed medicines and the ongoing sustainability of the PBS.

This CRIS describes the cost recoverable activities that have contributed to the achievement of Outcome 2 (Program 2.3) as outlined in the 2023-24 Health Portfolio Budget Statement.

Outcome 2: Individual Health Benefits

Ensuring improved access for all Australians to cost-effective and affordable medicines, medical, dentaland hearing services; improved choice in health care services, through guaranteeing Medicare and the Pharmaceutical Benefits Scheme; supporting targeted assistance strategies and private health insurance.

Program 2.3: Pharmaceutical Benefits

Provide all eligible Australians with reliable, timely, and affordable access to high quality, cost-effective, innovative, clinically effective medicines, and sustainable pharmaceutical services by subsidising the cost of medicines through the Pharmaceutical Benefits Scheme (PBS) and the Life Saving Drugs Program (LSDP).

**Why is charging appropriate for the regulatory activity?**

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 Government implemented revised CRGs 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 is a non-corporate Commonwealth entity.

The 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.

**Who will pay the regulatory charges?**

The PBAC considers medicine/vaccine applications and contemplates the views of medical bodies, health professionals, individual consumers of medicines and their representatives. Applicants request the regulatory effort of having their medicine listed and maintained on the PBS/NIP as a result of these considerations.

All applicants are charged fees for services provided, unless the applicant successfully applies to have the fee waived on public interest and financial viability grounds, or the application meets the specified criteria for a fee exemption.

Policies and processes relating to fee exemptions and fee waivers have been approved by Government and are stipulated in the supporting regulations.

1.3 New and amended cost recovery arrangements commencing 1 July 2023

**What changes have been made to cost recovery activities?**

Annual review of indexation for PBAC cost recovery fees

The Department has conducted the annual review of cost recovery fees for the 2023-24 financial year. Further information regarding the review can be found at section 3.2.1 (page 14) of this document. Fees for 2023-24 can be found at table 7 (page 15). These fees will commence on 1 July 2023.

Commencement of Ministerial determination request (stockholding) charging pathway

Consistent with commitments made in the 2022 Strategic Agreement with the Medicines Industry, 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 legal obligations of supply. Such applications have been accepted by the Department since October 2022.

Similar to existing types of list management application, these applications require Departmental assessment and processing. To ensure consistency with existing cost recovery arrangements and the Australian Government Charging Framework, Ministerial determination requests will be subject to cost recovery from 1 July 2023. The fee, as noted in table 7 (page 15), is $4,880. Only Ministerial determination request (stockholding) applications received from 1 July 2023 will be subject to cost recovery.

Amendments to Ministerial Discretion requests for Statutory Price Reductions (SPRs)

Under the current arrangements, sponsors of PBS-listed medicines subject to a SPR may apply to the Department requesting Ministerial discretion to reduce or abstain from a SPR. These Ministerial discretional applications require Departmental assessment and processing. Commitments made in the 2022 Strategic Agreement with the Medicines Industry provide for new variations of catch-up price reductions for combination items and first new brands listed on the PBS. The Minister has retained the discretion to reduce or not apply these new types of SPR and consequently sponsors may apply to the Department requesting Ministerial discretion.

Ministerial discretion requests regarding catch-up and first new brand SPRs will be subject to cost recovery from 1 July 2023. These cost recovery arrangements will remain identical to existing Ministerial discretion requests.

**2. POLICY AND STATUTORY AUTHORITY TO COST RECOVER**

2.1 Government policy approval to cost recover the regulatory activity

**When and what did the government announce?**

In the 2008-09 Budget, the Government announced that costs associated with the listing of medicines on the PBS and designated vaccines for the NIP would be recovered from applicants. Cost recovery, via fees for services provided, commenced on 1 January 2010 and was indexed by Consumer Price Index (CPI) up until 2019.

The 2018-19 Mid-Year Economic and Fiscal Outlook (MYEFO) measure: *Improving Access to Medicines — streamlined listings* provided Government approval for the first stage of PBS process improvements and related cost recovery. Existing fees were also revised to reflect the efficient costs of services provided to industry during the PBS listing process of 2019. Following stakeholder feedback and to reduce the impact on applicants, Government agreed to the staged increase of existing fees (50 per cent in July 2019 with the remaining 50 per cent in July 2020).

In June 2020, Government agreed to implement ATAGI fees from 1 July 2020, and to further delay implementation of deed management fees until Stage 2 implementation.

The 2020-21 Budget measure: *Improving Access to Medicines — Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme — new and amended listings* provided Government approval for the second stage of PBS process improvements and consequential cost recovery arrangements including new fees for deed management activities. Stage 2 PBS process improvements and related cost recovery changes came into effect on 1 January 2021. Fees approved by Government are indexed annually in line with the Australian Government Charging Framework.

The 2023-24 Budget measure: *Portfolio Charging Review Outcomes – Cost Recovery Arrangements for Health Technology Assessment* provided Government approval to implement cost recovery arrangements for Ministerial determination requests, also known as Stockholding requests.

**PBS list regulatory activities undertaken but not charged – PBS levy related activity**

Consultation with industry in early 2018 included the application of a PBS listing levy for activities where the work undertaken cannot be directly attributed to an individual sponsor, and to cover the cost of fees waived on certain grounds to achieve policy outcomes. Under the Australian Government Charging Framework, these types of costs can be recovered as an annual levy.

For example, activities such as maintaining the currency of information about the medicine and ensuring the medicine’s price is compliant with the legislation ensure the ongoing clinical and cost effectiveness of PBS medicines and Australian patients’ ongoing access to medicines. These activities are of benefit to those who cause regulatory effort.

The levy proposed in consultation would have applied to each PBS listed medicine and total approximately $5 million per annum in cost recovered revenue (estimate for 2018-19). Industry raised strong concerns about the additional cost and being charged for these non-requested activities (e.g. price disclosure and statutory price reductions). Consultation also determined there would be an impact on listings on the PBS under this proposed approach.

In 2018-19, the former Government decided not to apply a PBS listing levy and the relevant activities continue to be funded by the Government via an appropriation to the Department. This partial cost recovery approach may change as a result of any review of the cost recovery arrangements currently in place.

2.2 Statutory authority to charge

Section 99YBA in Division 4C—Cost recovery of the *National Health Act 1953* provides for regulations setting out the fees to be charged to recover costs to the Commonwealth of providing certain services. The regulations may make provisions in relation to services outlined in Section 9B (Provision of Vaccines) and Part VII (Pharmaceutical Benefits) of the Act. The [*National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022*](https://www.legislation.gov.au/Details/F2019C00540)(the Regulations) provide authority for cost recovery charges for services provided to list and manage items on the PBS/NIP.

**Legislative amendments**

Cost recovery regulations

On 1 July 2023 the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2022* (the Regulations) will be amended. The amendments to the Regulations will make three key changes:

* Fees will be indexed for 2023-24;
* The Ministerial determination request (stockholding) charging pathway will commence; and
* Amendments to the existing Ministerial discretion request charging pathway to reflect additional types of ministerial discretion that may be sought by applicants will commence.

The Regulations can be accessed via the [PBS website](https://www.pbs.gov.au/info/industry/listing/elements/fees-and-charges) or on the Federal Register of Legislation.

**3. COST RECOVERY MODEL**

3.1 Regulatory activities included in the model

Cost recovery fee categories are as follows, with the activity descriptions detailed in Tables 1-5:

* *Section 3.2.1 – ATAGI pre-submission advice (evaluation);*
* *Section 3.2.2 – PBAC pre-submission meetings;*
* *Section 3.2.3 – Submission Services including Notice of Intent;*
* *Section 3.2.4 – Pricing Services including Notice of Intent for Pricing;*
* *Section 3.2.5 – PBS List Management Services.*

For the cost breakdowns of the different fee categories please refer to Table 8.

**3.1.1 ATAGI pre-submission advice (evaluation)**

ATAGI pre-submission advice (evaluations) is an existing service 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.

Cost recovery arrangements for this activity were introduced on 1 July 2020. A fee waiver or fee exemption may apply for eligible applications – refer to the Cost Recovery Administrative Guidelines and/or Part 7 of the Regulations. Fee Waiver and Fee Exemption requests for ATAGI advice are considered as part of the ATAGI application process.

On 1 July 2022 the Notice of Intent step for ATAGI applications was implemented. This supports increased planning time for applications seeking ATAGI advice. Additional information regarding the Notice of Intent step is provided in section 3.1.3.

There are two types of vaccine submissions - complex and simple as outlined below.

**Table 1 – ATAGI pre-submission evaluation activity description**

| Fee Category | Description |
| --- | --- |
| ATAGI - Complex application | An ATAGI application is in the complex category if the Secretary determines that considering the application will require extensive, or complex, data analysis and review. |
| ATAGI - Simple application | An ATAGI application is in the simple category if the Secretary determines the application is not in the complex category. |

Note: The [ATAGI procedures document](https://www.health.gov.au/resources/publications/atagi-pre-submission-advice) available on the Department’s website outlines the criteria for complex and simple applications.

**3.1.2 PBAC Pre-submission meetings**

Pre-submission meetings are an applicant-driven service for the Department to provide formal (non‑binding) advice to applicants on the preparation of certain submissions to the PBAC. These services are an optional component of the PBS listing process. Fees only apply where an applicant has requested a meeting.

There are two types of pre-submission meetings, as outlined below.

**Table 2 – PBAC pre-submission meeting activity description**

| Fee Category | Description |
| --- | --- |
| First meeting | The initial pre-submission meeting between an applicant and the Department in relation to a PBAC submission. |
| Second meeting | A second or subsequent pre-submission meeting applies if a first meeting has been previously convened and invoiced in relation to a PBAC submission. |

**3.1.3 Submission Services including Notice of Intent**

Submission services include cost recovered evaluation activities that are a mandatory part of the PBS listing process. Fees are charged when the Notice of Intent or submission (where a Notice of Intent exception applies) is lodged with the Department.

A Notice of Intent must be lodged for all PBAC submissions. This supports increased planning time which will permit the progression of all submissions through to the PBAC, by allowing the Department time to prepare and resource all incoming identified assessments to support efficiency and provide certainty.

A fee waiver or fee exemption may apply for eligible applications – refer to the Cost Recovery Administrative Guidelines and/or Part 7 of the Regulations.

PBAC submission services are outlined below.

**Table 3 – PBAC submission activity description**

| Submission  Fee Category | Description |
| --- | --- |
| Notice of Intent | A Notice of Intent form must be completed and lodged with the Department at least 20 business days prior to lodgement of a PBAC submission and each ATAGI submission. The Notice of Intent form must include the applicant’s nominated evaluation category based on the type of submission being lodged. The Notice of Intent fee is a non-refundable administrative fee that is invoiced together with the submission services fee (that generally reflects the evaluation category). A Notice of Intent form is not required for generic submissions. Notice of Intent lodgement timeframes vary for resubmission pathways. |
| Category 1 | Category 1 submissions involve a request for PBS or NIP listing of one or more of the following:   * A first in class medicine or vaccine, and/or a medicine or vaccine for a new population; or   + *A first-in-class medicine or vaccine represents a drug or vaccine with a unique mechanism of action that has not been considered by the PBAC; and/or*   + *A new population could include a disease or medical condition not previously considered by the PBAC.* *A disease is intended to cover whole diseases when all stages and genetic subtypes are considered.* * A drug with a codependent technology that requires an integrated codependent submission to the PBAC and Medical Services Advisory Committee (MSAC); or * A drug or designated vaccine with a Therapeutic Goods Administration (TGA) Provisional determination related to the proposed population.   Where multiple submissions are lodged at the same time, the Category 1 fee will apply to each submission that meets the Category 1 criteria.  Activities include evaluation of new clinical or economic information that is supported by an economic evaluation and financial analysis, DUSC and ESC consideration. These submissions may require additional interaction between the PBAC Secretariat and either TGA representatives or MSAC Secretariat and the PBAC to progress these submission types. |
| Category 2 | Category 2 submissions generally relate to request a PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication; and do not meet the criteria for a Category 1 submission.  Category 2 may also relate to a request for the PBAC to reconsider an existing recommendation where there is a change to the clinical, economic and/or financial information most recently relied on by the PBAC.  A Category 2 submission may be required for a new form or strength of an already-listed medicine or vaccine that is not bioequivalent to an existing listed form of the medicine or vaccine. This may be necessary to demonstrate that the new form delivers similar clinical outcomes to the existing form. Activities include evaluation as per Category 1 and ESC consideration. |
| Category 3 | Category 3 submissions generally relate to requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission. This includes requests to enter into a deed or vary an existing deed. Although the PBAC will assess the clinical need for and clinical effectiveness of the requested listing, an economic evaluation is not necessary to support the claims made in the submission. Additionally, the financial estimates do not require the PBAC to assess any substantial financial implications for the supply of a listed medicine or designated vaccine.  Category 3 may also relate to a request for the PBAC to reconsider an existing recommendation where there is no change to the clinical, economic or financial information most recently relied on by the PBAC.  As PBAC advice is required on a case-by-case basis regarding the potential for schedule equivalence for biosimilar listings, Category 3 submissions are also appropriate for a new biosimilar brand of an existing pharmaceutical item with no indication changes.  PBAC advice may also be required through a Category 3 submission process in some other circumstances (e.g. requests for PBS listing of nutritional products (medicinal foods) or some new brands of existing pharmaceutical items with an unusual presentation; or advice on potential equivalence, substitution, or issues related to quality use of medicines).  Activities include departmental assessment of claims made in the submission. |
| Category 4 | Category 4 submissions involve a request for one or more of the following:   * Listing of a new pharmaceutical item of a listed medicine; * Consideration as an exempt item; * Including a listed medicine on the prescriber bag or varying an existing prescriber bag listing; * A change/new manner of administration of a listed medicine; * A change to the maximum quantity and/or number of repeats of a listed medicine; or * A change or addition to the prescriber type(s) of a listed medicine.   Activities include evaluation as per Category 3, consideration by the PBAC Executive and ratification by the PBAC. |
| Committee secretariat | Committee secretariat submissions relate to applications where the requested listing changes do not require the PBAC to consider comparative effectiveness, cost-effectiveness or clinical need:   * there is no difference in patient safety or population for the new pharmaceutical item in the submission compared to an already-listed pharmaceutical item; and * there is no financial impact from the proposed change to the PBS. |
| Generic listing of a new brand or new oral form of existing  pharmaceutical item | These applications do not require PBAC consideration for listing an additional brand (a generic medicine) or new oral form of an existing TGA-approved and PBS-listed pharmaceutical item. Evidence of equivalence from the TGA must also be provided. However, applications that relate to Somatropin (growth hormone), are classified as Category 3. |

| Resubmission  Fee Category | Description |
| --- | --- |
| Early Resolution Pathway  *(optional)* | This pathway applies where the PBAC has nominated based on independent assessment of the submission, considers the issues identified can be easily resolved and the medicine or vaccine represents high added therapeutic value (HATV); and the applicant accepts the nomination via the Notice of Intent form.  Activities include departmental assessment of claims made in the submission and out-of-session PBAC reconsideration (where possible).  Where an applicant chooses not to accept the PBAC nominated pathway; addresses issues other than those identified by the PBAC; or is unable to meet the lodgement timeframes, the Standard Re-entry Pathway would apply. |
| Facilitated Resolution Pathway  *(optional)* | This pathway applies where the PBAC nominates the pathway based on independent assessment and identification of the issues to be resolved through a workshop; the medicine or vaccine represents HATV; and the applicant accepts the nomination via the Notice of Intent form.  Activities include a post-PBAC meeting with the Chair to determine the workshop agenda, a workshop with PBAC members (relevant to workshop outcomes) and evaluation of new information as per Category 2 submissions.  Where an applicant chooses not to accept the PBAC nominated pathway; or is unable to meet the lodgement timeframes, the Standard Re-entry Pathway would apply. |
| Early Re-entry Pathway  *(optional)* | This pathway only applies where the PBAC has nominated the pathway based on their independent assessment of the submission and considers the issues identified can be easily resolved; and the applicant accepts the nomination through the Notice of Intent form.  Activities include departmental assessment of claims made in the submission and early PBAC reconsideration.  Where an applicant chooses not to accept the PBAC nominated pathway; addresses issues other than those identified by the PBAC; or is unable to meet the lodgement timeframes, the Standard Re-entry Pathway would apply. |
| Standard Re-Entry Pathway | This pathway is the default pathway for resubmissions following a ‘not recommended’ PBAC outcome and also applies where:   * an applicant chooses not to accept the PBAC nominated pathway; or * an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or * the PBAC does not nominate a resubmission pathway; or * an Early Re-entry, Early Resolution or Facilitated Resolution resubmission receives a ‘not recommended’ outcome; or * an applicant decides to lodge their resubmission later than allowable for other pathways.   Activities include evaluation or assessment of the claims made in the submission. |
| Independent Review  *(optional)* | Independent reviews are available for applicants where the PBAC has declined to recommend the listing of a new drug on the PBS or in certain circumstances where PBAC has not recommended the listing of an additional indication of an already listed drug. |

**3.1.4 Pricing Services including Notice of Intent for Pricing**

Pricing services include existing cost recovered activities that are a mandatory part of the PBS listing process. A fee waiver or fee exemption may apply for eligible applications – refer to the Cost Recovery Administrative Guidelines and/or Part 7 of the Regulations.

A Notice of Intent for Pricing must be submitted for all pricing applications. The Notice of Intent for Pricing allows time for the Department to prepare and resource all incoming identified pricing applications to support efficiency and provide certainty. It also assists with monitoring and data collection.

Following a positive recommendation from PBAC, applicants can elect to proceed to pricing services to reach a listing arrangement for the PBS. For information on NIP listing processes refer to the Department’s website. PBS Pricing Services are outlined below.

**Table 4 - PBS pricing services activity description**

| Fee Category | Description |
| --- | --- |
| Notice of Intent for Pricing | Notice of Intent for Pricing includes whether a sponsor intends to submit a pricing offer and by when; not submit a pricing offer; or return to the PBAC for re-consideration.  Where an applicant intends to submit a pricing application, the Notice of Intent must include the pricing pathway which reflects the listing arrangements sought. The Notice of Intent fee is a non-refundable deposit that is invoiced together with the fee for pricing services.  No fee will be charged where the Notice of Intent Pricing Form reflects a ‘No’ response. |
| Pricing Pathway A *(facilitated)* | This pathway only applies where PBAC has nominated the pathway based on the criteria in section 42 of the Regulations and the applicant accepts the nomination via the Notice of Intent for Pricing form.  Activities include allocation of a departmental case manager, negotiation and finalisation of PBS listing arrangements and rebate management services. |
| Pricing Pathway B (New deed) | This pathway applies for submissions which require negotiation and finalisation of a new deed of agreement where there are no similar arrangements in place. This could include an assessment of proposed risk-sharing, managed entry and/or special pricing arrangements.  Activities include negotiation and finalisation of PBS listing arrangements and rebate management services. |
| Pricing Pathway C (Existing deed) | This pathway applies to submissions which require third-party responsible person notification of changes to an existing deed of agreement, and/or where an applicant has received a positive PBAC recommendation to list within the scope of existing PBS arrangements, whether these relate to the new listing or to another existing listing.  Activities include negotiation and finalisation of PBS listing arrangements and rebate management services. |
| Pricing Pathway D (Standard listing) | This pathway applies to submissions that do not involve negotiation of a new or existing deed of agreement.  Activities include finalisation of PBS listing arrangements |
| Pricing Secretariat | An application is in the Pricing Secretariat category if it is not in the Pricing Pathway A, B, C, or D category. This category is intended for the simplest of applications. The pathway applies to changes to listings of existing medicines which do not require a new price. |
| Rebate management services | Includes administration of the terms and conditions of the deed of agreement to enable the PBS listing to continue and includes the regular processing of the PBS expenditure rebates payable to the Commonwealth that enable the PBS listing to continue throughout the (five year) term of the deed.  The rebate management fee is charged upfront and is included in the Pricing Pathway A, B and C fees and also when a deed is renewed. |

**3.1.5 PBS List Management Services**

The PBS list management activities include applicant driven services to manage the PBS listing. Price increase requests, brand premium requests and Ministerial discretion 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. for two different strengths). This reflects the work effort associated with these application types as these applications are assessed by the Department per pharmaceutical item.

PBS list management services are outlined below.

**Table 5 - PBS List Management requested activities description**

| Fee Category | Description |
| --- | --- |
| Price increase request (including brand premiums) | Applicants may seek the Minister (or delegate) to consider a request a price increase for a particular product listed on the PBS. |
| Ministerial discretion request | Applicants may seek the Minister (or delegate) consider the statutory price reduction or cumulative effects of other price reductions are not to apply. |
| Deed renewal request | Applicants may seek to renew a deed agreement at the cessation of the existing five year deed term. Activities include re-negotiation and on what terms the existing deed should be renewed under s85E of the *National Health Act 1953* and rebate management services. |
| Deed variation request | Applicants may seek to vary the terms of an existing deed (within the current deed term). Activities include negotiation of the terms the existing deed should be varied under s85E of the *National Health Act 1953.* |
| Ministerial determination request (Stockholding request) | Applicants may request a determination of the Minister (or a delegate) to alter stockholding arrangements to remain compliant with their legal obligations to supply a minimum quantity of certain PBS-listed medicines within Australia. |

3.2 Costs of the regulatory charging activity

For the 2023-24 financial year, the total regulatory effort required by the Department to deliver services related to PBS and NIP listing activities is estimated to be $39.70 million.

The current cost recovery regulations provide waivers and exemptions for sponsors if their submissions satisfy the criteria. Fee waivers and fee exemptions are available across all charging categories, with the exception of pre-submission meetings. The estimated cost for waivers and exemptions granted is $2.61 million. In addition, PBS list regulatory activities (see Section 2.1), estimated to cost $5.42 million, are not cost recovered.

|  |  |
| --- | --- |
| **Table 6 - PBS cost recovery activity and cost summary for 2023-24** | **Estimated Cost for 1 July 2023 – 30 June 2024 ($ million)** |
| ATAGI Pre-submission Evaluation | $0.99 |
| Pre-submission Meetings | $1.14 |
| Notice of Intent | $0.13 |
| PBAC Submission Evaluation | $24.83 |
| PBS Pricing Services | $4.03 |
| PBS List Management Services | $3.17 |
| PBS List Regulatory Activities | $5.42 |
| **Total** | $39.70 million |

Table 7 details the cost recovery fees and revenue estimates for 2023-24. The estimated volumes exclude waivers and exemptions. With consideration to revenue forgone due to waivers and exemptions, the total revenue is estimated to be $32.06 million.

The Independent Review fee is included in this table based on the charging approach used for the Category 2 evaluation fee. As there have been no independent review applications submitted over the past five years, there is no revenue estimated for this category.

**3.2.1 Outcome of annual review of cost recovery arrangements for 1 July 2023**

Prior to the commencement of each financial year the Department conducts a review of PBS/NIP listing and management fees. The activity based costing methodology previously agreed by Government remains the basis for charging. Indexation is applied to all fees to reflect the current efficient costs of delivering the services. This approach is consistent with other cost recovery arrangements across the Department. Previously, the annual review for the 2022-23 financial year resulted in a decrease in fees ranging from 0.7 to 5.9%.

The annual review for the 2023-24 financial year has resulted in an increase to fees. On average, fees have increased by 6.22% (ranging from 2.05% to 19.42%) compared to fees charged in the 2022-23 financial year. There are a number of drivers impacting these fee changes including:

* + Staff salary rates have increased by an average of 5.1%;
  + Supplier and IT costs have increased by 2.2%;
  + Overhead costs have increased by 6.1%; and
  + Depreciation costs, primarily relating to the ongoing build of the Health Products Portal (HPP), have increased by 9.8%.

Costs relating to the evaluation of complex PBAC submissions by external health technology assessment groups have also increased as a result of increasing complexity of evaluations. Consequently, the Government has provided additional funding to ensure that complex PBAC submissions can continue to be appropriately evaluated by the Department. This is reflected in a 13.1% increase to supplier costs associated with categories 1, 2, Standard Re-entry and Facilitated Resolution submissions.

Similarly, the costs related to the evaluation of ATAGI submissions by external health technology assessment groups have increased. New panel arrangements for ‘Health Technology Assessment and Support Services’ were finalised in April 2023. As a result of these new panel arrangements, supplier costs for both complex and simple applications have increased by an average of 23.2%. This is the first time these evaluation costs have increased since the commencement of cost recovery arrangements for ATAGI applications on 1 July 2019.

Further information regarding these costs and how they impact cost recovery fees is available in section 3.2.3 (page 15) and table 8 (page 16).

Additionally, the Department is currently undertaking a ‘time and motion study’, reviewing the level of Departmental staff effort involved in the administration of PBAC submissions. It is anticipated that the results of the study will identify efficiencies throughout the PBAC submission process. Any efficiencies found will be reflected in amended fees charged in the 2024-25 financial year. This study commenced following an independent review of the activity-based costing model, discussed below.

**3.2.2 Independent Review of the activity based costing model**

An independent review of the activity based costing model for PBS listing and management fees was completed on 30 June 2022. The review made four primary recommendations:

* Confirm that the PBAC cost model will be reviewed and updated (as necessary) as proposed in 2022-23, including cost model documentation and supporting documentation (i.e., user guides);
* Ensure that mechanisms are in place so that where prices are set using an indexation mechanism, that they are also reflective of minimum efficient costs;
* Commit, publicly, to undertake a full cost model refresh during the 2022-23 financial year, with outcomes to be reflected in fee updates when completed, except where legislative or policy issues are identified, and further Government consideration may be required; and
* Consider whether the PBS CRIS adequately documents the stakeholder engagement strategy including a summary of the latest engagement round – who was consulted and when, what their views were, and whether/how these views have been considered. Better practice would also identify planned consultation processes and mechanisms to be used to seek stakeholder feedback.

These four recommendations have informed the Portfolio Charging Review (PCR) undertaken by the Department, in conjunction with the Department of Finance, in 2022. Outcomes from the PCR will be reported in the 2023-24 financial year.

**3.2.3 Fees and costs from the activity-based costing model**

**In line with the CRGs, the activity-based costing model includes the following costs**[[2]](#footnote-2)**:**

**Direct costs: allocation of direct costs included in this model are staff salaries (including on-costs for superannuation and leave) for those directly involved in the activity, committee costs and supplier costs (e.g. contractors, consultants and legal).**

**Indirect costs: cannot be easily linked or where tracking this outweighs the benefits. Indirect costs are allocated as overheads for staff directly involved in performing the activities using the Department of Finance’s approved costing methodology. Indirect costs include staff training and development, workers compensation premium, human resources support, organisational services, desktop ICT services and property operating expenses.**

**Capital costs: IT system depreciation costs associated with the PBS/NIP listing processes.**

**Activity based costing methodology has been applied to allocate costs to activities and outputs using volume-based cost drivers. This method enables more informed analysis of the efficiency of outputs and business processes. Costs were estimated on the following basis:**

* **The regulatory activities to be delivered were identified in consultation with relevant staff;**
* **PBAC costs were estimated based on the number of members and meetings, and include wages/salary of members, travel allowances, accommodation, flights and catering as applicable;**
* **The number of submissions per year is the average number of submissions over a 3-year period;**
* **Supplier costs were based on signed contracts; and**
* **Staff costs/overheads include salaries as advised by the Department of Finance.**

**Table 7 - 2023-24 fees, effective from 1 July 2023 with estimated volumes and revenue for 2023-24**

| **Charge** | **Type** | **Fee from 1 July 2023** | **Estimated Volume** | **Estimated Revenue for 1 July 2023– 30 June 2024 ($m)** |
| --- | --- | --- | --- | --- |
| **ATAGI Pre-submission Evaluation** |  |  |  |  |
| Complex Submission | Fee | $212,360 | 3 | $0.64 |
| Simple Submission | Fee | $116,960 | 3 | $0.35 |
| **Pre-Submission Meetings** |  |  |  |  |
| 1st Pre-Submission Meeting | Fee | $15,440 | 60 | $0.93 |
| 2nd Pre-Submission Meeting | Fee | $20,980 | 10 | $0.21 |
| **Notice of Intent Submissions** |  |  |  |  |
| Notice of Intent[[3]](#footnote-3) | Fee | $430 | 293 | $0.13 |
| **Submission Services (PBAC Evaluation)** |  |  |  |  |
| Category 1[[4]](#footnote-4) | Fee | $252,110 | 15 | $3.78 |
| Category 2 | Fee | $197,500 | 48 | $9.48 |
| Category 3 | Fee | $42,460 | 34 | $1.44 |
| Category 4 | Fee | $32,940 | 32 | $1.05 |
| Resubmission - Standard re-entry | Fee | $195,390 | 24 | $4.69 |
| Resubmission - Facilitated resolution pathway[[5]](#footnote-5) | Fee | $269,020 | 2 | $0.54 |
| Resubmission - Early resolution | Fee | $41,190 | 5 | $0.21 |
| Resubmission - Early re-entry | Fee | $41,040 | 18 | $0.74 |
| Secretariat Submission | Fee | $11,560 | 6 | $0.07 |
| Generic Submission | Fee | $6,410 | 155 | $0.99 |
| Independent review | Fee | $197,500 | 0 | $- |
| **PBS Pricing Services** |  |  |  |  |
| Pricing Pathway A[[6]](#footnote-6) | Fee | $139,850 | 5 | $0.70 |
| Pricing Pathway B6 | Fee | $110,770 | 8 | $0.89 |
| Pricing Pathway C6 | Fee | $73,350 | 19 | $1.39 |
| Pricing Pathway D | Fee | $19,620 | 26 | $0.51 |
| Pricing Secretariat | Fee | $12,000 | 6 | $0.07 |
| **PBS List Management Services** |  |  |  |  |
| Deed Variations | Fee | $1,990 | 6 | $0.01 |
| Deed Renewals6 | Fee | $10,820 | 30 | $0.33 |
| Price Increases | Fee | $4,980 | 369 | $1.84 |
| Ministerial Discretion Request | Fee | $6,910 | 26 | $0.18 |
| Ministerial determination (stockholding) request | Fee | $4,880 | 182 | $0.89 |
| Rebate Management Service fee | Fee | $8,640 | 0 | $- |
| **Total** |  |  |  | **$32.05** |

**Table 8 - Unit cost per activity with breakdown for 2023-24**

| **Estimated Unit Cost per Activity** | **Direct Costs** | **Indirect Costs** | **Capital** | **Total Cost** |
| --- | --- | --- | --- | --- |
| **ATAGI Pre-submission Evaluation** |  |  |  |  |
| Complex Submission | $210,523 | $1,839 | $0 | $212,362 |
| Simple Submission | $115,709 | $1,248 | $0 | $116,957 |
| **PBAC Pre-Submission Meetings** |  |  |  |  |
| 1st Pre-Submission Meeting | $12,201 | $2,050 | $1,183 | $15,435 |
| 2nd Pre-Submission Meeting | $16,623 | $2,764 | $1,591 | $20,979 |
| **Prior Notice** |  |  |  |  |
| Notice of Intent | $333 | $60 | $35 | $429 |
| **Submission Services (PBAC Evaluation)** |  |  |  |  |
| Category 1 | $227,672 | $15,399 | $9,041 | $252,112 |
| Category 2 | $182,885 | $9,179 | $5,440 | $197,504 |
| Category 3 | $35,374 | $4,451 | $2,639 | $42,464 |
| Category 4 | $26,176 | $4,245 | $2,523 | $32,944 |
| Resubmission - Standard re-entry | $180,672 | $9,243 | $5,472 | $195,387 |
| Resubmission - Facilitated resolution pathway | $251,823 | $10,849 | $6,345 | $269,017 |
| Resubmission - Early resolution | $33,825 | $4,626 | $2,735 | $41,186 |
| Resubmission - Early re-entry | $33,713 | $4,606 | $2,723 | $41,042 |
| Secretariat Submission | $8,888 | $1,679 | $995 | $11,563 |
| Generic Submission | $4,947 | $918 | $542 | $6,407 |
| **PBS Pricing Services** |  |  |  |  |
| Pricing Pathway A6 | $111,518 | $17,839 | $10,498 | $139,855 |
| Pricing Pathway B6 | $88,927 | $13,753 | $8,087 | $110,767 |
| Pricing Pathway C6 | $59,679 | $8,604 | $5,069 | $73,352 |
| Pricing Pathway D | $15,252 | $2,749 | $1,620 | $19,620 |
| Pricing Secretariat | $9,308 | $1,691 | $998 | $11,996 |
| **PBS List Management Services** |  |  |  |  |
| Deed Variation Request | $1,977 | $14 | $0 | $1,991 |
| Deed Renewal Request6 | $10,773 | $47 | $0 | $10,820 |
| Price Increases | $3,862 | $702 | $413 | $4,976 |
| Ministerial Discretion Request | $5,468 | $917 | $529 | $6,913 |
| Ministerial Determination (stockholding) Request | $3,859 | $649 | $374 | $4,882 |
| Rebate Management Fee | $6,788 | $1,855 | $0 | $8,643 |

Table 9 below details the fee pay points supporting a consistent approach of upfront payment across all charging categories for PBS listing and management processes. These fee pay points occur prior to activity being undertaken and costs being incurred by the Department.

**Table 9 – PBS Listing and Management Process with Cost Recovery Fee Point**

| Category | ATAGI Pre-submission Evaluation Process |
| --- | --- |
| **ATAGI Pre-submission evaluation services** | Notice of Intent received informing of ATAGI Pre-submission category |
| ATAGI Notice of Intent and Pre-submission application Lodgement Fee Point |
| ATAGI Assessment |
| ATAGI advice |
| **Category** | **PBS Listing Process** |
| **PBAC Pre-submission meetings** | Request for pre-submission meeting received |
| Pre-submission Meeting Fee Point |
| Pre-submission meeting with sponsor |
| Review sponsor meeting outcome record |
| **Submission services (PBAC evaluation)**  (Submission categories and Resubmission Pathways) | Notice of Intent form received informing of submission evaluation type |
| Notice of Intent and application Lodgement Fee Point[[7]](#footnote-7) |
| PBAC Evaluation |
| Positive PBAC Recommendation |
| (Proceed to positive recommendation pathways) |
| OR |
| Rejected PBAC Recommendation (Proceed to resubmission pathways) |
| **Pricing services** | PBAC positive recommendation |
| Notice of Intent form received informing of the positive recommendation pathway |
| Notice of Intent and Positive Recommendation Pathway Fee Point10 |
| Pricing offer made |
| Pricing agreement reached |
| Adjustment to the invoicing based on the pricing agreement reached[[8]](#footnote-8) |
| Listing occurs |
| **Category** | **PBS Post Listing Process** |
| **List Management Services** | Request for post listing activity (i.e. price increase, ministerial discretion, ministerial determination (stockholding), deed renewal or deed variation requests) received |
| Post Listing Fee Point |
| Actioning the requested post listing activity |

**4. RISK ASSESSMENT**

A Charging Risk Assessment (CRA) was undertaken for the revised model in May 2023, with an overall risk rating of ‘low’. This was due to there being no change to the cost recovery activity or policy that was previously approved by the Government and no change to the existing approved fee structure.

**5. STAKEHOLDER ENGAGEMENT**

The Department’s stakeholder engagement strategy for cost recovery arrangements allows for regular, transparent and timely consultation with pharmaceutical industry stakeholders via the Access to Medicines Working Group (AMWG). The AMWG is the primary consultative, policy development and delivery forum for the Government and innovating medicines sector. It allows for stakeholder engagement on PBS cost recovery, ongoing PBS process improvements, and collaboration to address priorities of the Strategic Agreement. Meetings of the AMWG are held twice a year, with further consultation conducted out of session. Further information on the AMWG, including meeting communiques, can be found on the PBS website at <https://www.pbs.gov.au/info/general/access-medicines-working-group>.

Further public consultation occurs via industry comment on the CRIS. Prior to the current consultation process, the most recent CRIS consultation was undertaken in May 2023 before the publication of the final 2023-24 CRIS. Seven submissions were received from relevant medicine industry stakeholders. These submissions are summarised at **Attachment A,** alongside Departmental response to feedback raised in those submissions.

The outcomes of the current round of consultation regarding the draft 2023-24 CRIS are summarised and published at **Attachment A**.

**6. FINANCIAL ESTIMATES**

The forecast expenses of the partial cost recovery arrangements along with the estimated revenue for the 2023-24 financial year and three forward years are in Table 10 below.

There is an ongoing net deficit which is supplemented by a Government appropriation to the Department to cover the shortfall). Forward projections demonstrate the difference between expenses and revenue increases every year.

Should there be any change to the underlying cost recovery model, a new financial estimates table will be provided.

**Table 10 – Financial estimates for PBAC cost recovery activities for 2023-24 and three forward years**

| Forecast Financial Estimates | 2023-24  ($million) | 2024-25  ($ million) | 2025-26  ($ million) | 2026-27  ($ million) |
| --- | --- | --- | --- | --- |
| Combined Expenses = X | $39.70 | $40.64 | $41.32 | $42.05 |
| Combined Revenue = Y | $32.05 | $32.80 | $33.34 | $33.92 |
| Balance = Y – X | -$7.65 | -$7.84 | -$7.98 | -$8.13 |
| Cumulative Balance | -$37.43[[9]](#footnote-9) | -$46.50 | -$54.48 | -$61.38 |
| Balance management  strategy explanation | The continuing forecast under recovery of expenses represented in the growing size of the cumulative balance is due to the partial cost recovery arrangements in place, including post-listing activities that are not cost recovered along with revenue foregone from waivers and exemptions.  This will be monitored over time to ensure the degree of alignment between expenses and revenue is appropriate | | | |

**7A. FINANCIAL PERFORMANCE**

Table 11 below will be updated after each financial year to report on the actual financial performance.   
The forecast financial performance as published in the CRIS will be compared with the actual financial performance for each financial year. Any variance greater than 5 per cent will be identified and explained.

As PBS/NIP listings are only partially cost recovered, the aim of comparing the actual financial results with forecasted financial estimates over a 5-year period is to ensure that the degree of alignment of under‑recovery of costs is as agreed by the Government as part of the Department’s financial balance management strategy.

**Table 11: Financial performance for cost recovered activities**

| **Actual Financial Results** | **2019–20** | **2020–21** | **2021–22** | **2022–23** | **2023-24** |
| --- | --- | --- | --- | --- | --- |
| ($ millions) | ($ millions) | ($ millions) | ($ millions) | ($ millions) |
| Expenses = X | $29.59 | $31.44 | $31.76 | $32.88 |  |
| Revenue = Y | $19.51 | $22.53 | $26.90 | $26.95 |  |
| Balance = Y – X | -$10.08 | -$8.91 | -$4.86 | -$5.93 |  |
| **Cumulative balance** | **-$10.08** | **-$18.99** | **-$23.85** | -**$29.78** |  |
| Material variance explanation | The revenue in 2022-23 was $0.89 million (3%) lower than forecast and the actual expenses were $2.12 million (6%) lower than forecast. This is due to a combination of factors including the actual volume and range of submission types received compared to forecasts, and a higher number of withdrawn applications.  In 2022-23 there was a deficit of $5.93 million because of fee waivers, fee exemptions and forgone revenue from post-listing activities that are not cost recovered.  Revised cost recovery arrangements were introduced in 2019-20 where the cumulative balance was re-set. | | | | |
| Balance management strategy | Partial cost recovery arrangements are in place. The Australian Government is funding applications where fees are waived or exempt under legislation, as well as post-listing activities that are not cost recovered. | | | | |

**7B. NON-FINANCIAL PERFORMANCE**

The Australian Government Charging Framework has been developed to apply across the general government sector. It includes performance requirements based on Section 38 of the Public Governance, Performance and Accountability Act 2013 (the PGPA Act), which is ‘Measuring and assessing performance of Commonwealth entities’.

The non-financial performance of the activities explained in this CRIS is monitored through a set of requirements under subsection 99YBC (5) of the Act included in the Department’s annual report, consistent with the PGPA Act. The performance requirements are:[[10]](#footnote-10)

The Secretary must, as soon as practicable after June 30 in each year, prepare and give to the Minister a report on processes leading up to the Pharmaceutical Benefits Advisory Committee consideration, including:

1. the extent and timeliness with which responsible persons are provided copies of documents relevant to their submission to the Pharmaceutical Benefits Advisory Committee;
2. the extent to which responsible persons exercise their right to comment on these documents, including appearing at hearings before the Pharmaceutical Benefits Advisory Committee; and
3. the number of responsible persons seeking a review of the Pharmaceutical Benefits Advisory Committee recommendation.

**Ensuring access to cost-effective, innovative, clinically effective medicines through the PBS**

| Percentage of new medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) that are listed on the Pharmaceutical Benefits Scheme within 6 months of in-principle agreement to listing arrangements. | | | | | |
| --- | --- | --- | --- | --- | --- |
| *Source: Department of Health and Aged Care Annual Report 2022-23, p. 72.* | | | | | |
| **2022-23 Target** | **2022-23** | **2021-22** | **2020-21** | **2019-20** | **2018-19** |
| ≥80% | 100% | 100% | 100% | 100% | 100% |
| **Result:** Met | | | | |

Metrics to reflect PBS process improvements and target 2017 Strategic Agreement objectives have been developed by the Access to Medicines Working Group. A subset of agreed metrics are published annually on the [PBS website](https://www.pbs.gov.au/info/general/pbs-process-improvements).

**8. KEY FORWARD DATES AND EVENTS**

|  |  |
| --- | --- |
| Activity | Date |
| Update CRIS for 2024-25 | June 2024 |

**9. CRIS APPROVAL AND CHANGE REGISTER**

| Date of CRIS change | CRIS change | Approver | Basis for change |
| --- | --- | --- | --- |
| TBA 2023 | Approval of amended 2023-24 CRIS (V1.8) | First Assistant Secretary, Technology Assessment and Access Division | Updated for 2022-23 financial results |
| 1 July 2023 | Approval of the final 2023-24 CRIS (V1.7) | Minister for Health and Aged Care | Further clarification following consultation feedback. |
| 3 May 2023 | Approval for the consultation draft of 2023-24 CRIS (V1.7) | First Assistant Secretary, Technology Assessment and Access Division | Revised fees to reflect annual indexation in line with the Australian Government Charging Framework |
| 28 October 2022 | Approval for the final 2022-23 CRIS (V1.6) | First Assistant Secretary, Technology Assessment and Access Division | Reporting on financial and non-financial performance for 2021-22. |
| 1 August 2022 | Approval for the final 2022-23 CRIS (V1.5) | First Assistant Secretary, Technology Assessment and Access Division | Further clarification following consultation feedback. |
| 15 June 2022 | Approval for the consultation draft of 2022-23 CRIS (V1.4) | Acting First Assistant Secretary, Technology Assessment and Access Division | Revised fees to reflect annual indexation in line with the Australian Government Charging Framework |
| 22 April 2022 | Approval for update to 2021-2022 CRIS (V1.3) | Technology Assessment and Access Division | References to the new *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022* updated. |
| 30 November 2021 | Approval for the 2021‑2022 CRIS  (V1.2) | First Assistant Secretary, Technology Assessment and Access Division | Reporting on financial and non-financial performance for 2020-21. |
| 21 June 2021 | Approval for the 2021-2022 CRIS  (V1.1) | Acting First Assistant Secretary, Technology Assessment and Access Division | Further clarification on fees following consultation feedback. |
| 9 April 2021 | Approval of consultation draft of 2021-2022 CRIS (V1.0) | Assistant Secretary, Health Technology Assessment – Policy Branch | Revised fees to reflect annual indexation in line with the Australian Government Charging Framework |
| 1 December 2020 | Approval for the 2019-20 CRIS V1.3 release | Minister for Health | New regulatory charging activity and 2019-20 outcome statement |
| 24 September 2020 | Approval of consultation on the draft 2020-21 CRIS | Assistant Secretary, Health Technology Assessment – Policy Branch | Changes to the costing model to support stage 2 PBS process improvements (operational change) |
| 19 June 2020 | Approval for the 2020-21 CRIS V1.0 release | Acting Secretary for Health | Updated to reflect introduction of ATAGI fees (operational change) |
| 9 December 2019 | Reporting on financial performance | First Assistant Secretary, Technology Assessment and Access Division | 2018-19 outcome statement |
| 11 June 2019 | Approval of the 2019-20 CRIS V2.0 | Minister for Health | Revalidation of the costing model – to reflect delay to ATAGI and deed management fees (policy change) |
| 18 May 2019 | Approval of consultation on the draft 2020-21 CRIS | Assistant Secretary, Health Technology Assessment – Policy Branch | Updated to reflect introduction of ATAGI fees (operational change) |
| 10 April 2019 | Approval for the CRIS 2019-20 V1.0 release | Minister for Finance and the Public Service | New regulatory charging activity |
| 13 March 2019 | Agreement to the  2019-20 CRIS V1.0 | Minister for Health | New regulatory charging activity |
| 7 March 2019 | Certification of the CRIS | Secretary for Health | To ensure compliance with Australian Government Cost Recovery Guidelines and Government |

**9. ATTACHMENT A – SUMMARY OF MAIN STAKEHOLDER VIEWS ON REQUIRED CRIS CONSULTATION AND RELATED DEPARTMENT RESPONSES 2023-24**

|  |  |
| --- | --- |
| **Stakeholder Comment** | **Response** |
| *Fee changes for 2023-24* | |
| Stakeholders sought greater clarity on the reasons for the increase in cost recovery fees for 2023-24. Stakeholders raised specific concerns regarding increases to the following charging categories:   * Category 1 * Category 2 * Standard re-entry * Facilitated resolution pathway * ATAGI – Complex submission * ATAGI – Simple submission   Additionally, stakeholders sought clarification on the utilisation of additional appropriated funds provided by Government. | The CRIS has been prepared in line with Department of Finance guidance, consistent with the Australian Government Cost Recovery Guidelines.  Cost recovery fees are calculated using an activity-based cost model. This ensures that the minimum efficient cost incurred by the Department in its performance of the cost recovered activities is accurately reflected in the fees charged.  The annual review of cost recovery fees has identified a number of factors leading to increase in the cost base for 2023-24. This includes increases to staff salary rates, supplier and IT related costs, overhead costs including staff training, human resources and property operating expenses and depreciation costs primarily relating to the ongoing build of the Health Products Portal (HPP).  Additionally, complex submission categories including Category 1, Category 2, Standard Re-entry and Facilitated Resolution submissions have seen additional increases in costs. As part of the 2023-24 Budget, Government decided to provide additional funding to ensure that complex PBAC submissions continue to be robustly evaluated. This funding was provided in response to the rising complexity of PBAC submissions and will ensure that the Department can continue to employ staff with appropriate health technology assessment (HTA) expertise, as well as engage HTA assessment groups, for the evaluation of complex PBAC submissions. As this funding is directly attributable to complex PBAC submission categories, Government agreed that it will be cost recovered via the fees for these complex submission categories. This funding does not impact fee changes to all other charging categories.  Costs related to both complex and simple ATAGI applications have also seen increases. The primary driver behind these increases is the commencement of new panel arrangements for the engagement of HTA groups to conduct evaluation of ATAGI applications. The previous panel arrangements had expired after remaining unchanged since the commencement of ATAGI cost recovery arrangements on 1 July 2019. The updated panel costs have been appropriately incorporated into the ATAGI application cost base for 2023-24. |
| *Timely notification of fee changes* | |
| Stakeholders highlighted the need for earlier stakeholder engagement to allow stakeholders adequate time for business planning and adjustment to fee changes. | The Department acknowledges the advance planning required by prospective applicants prior to making submissions and notes the consequential need for timely stakeholder engagement regarding changes in fees and other administrative changes that may occur.  The Department will prioritise the provision of additional lead time, stakeholder consultation and engagement with Medicines Australia ahead of the commencement of any fee and administrative changes in 2024-25. |
| Stakeholders requested the implementation of the 2023-24 PBAC/NIP cost recovery fees to be delayed until 1 January 2024. | The implementation date of 1 July 2023 for the commencement of cost recovery of stockholding applications, changes to ministerial discretion applications and associated amendments to the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022* was agreed to by Government in the 2023-24 Budget and is legislated. Aligning any changes with the commencement of the financial year where possible also ensures compliance with the Australian Government Charging Framework. The Department is therefore unable to alter the date of implementation. |
| *Cost recovery levy* | |
| Stakeholders requested the removal of several statements in section 2.1 of the CRIS, regarding a previously proposed levy which would have cost recovered applicant driven post-listing activities. | The Department notes prior feedback relating to the potential impact of the previously proposed levy on post-listing activities.  The Department views the existing statements on this matter in the CRIS as a factual account of the previous decision made by Government not to implement the levy. These statements also accurately reflect both the current state and the reasoning behind the partial cost recovery arrangements currently in place, as opposed to full cost recovery, which would also include the implementation of the levy.  There are currently no proposed changes to existing policy settings for existing partial cost recovery arrangements.  The Department continues to remain committed to ongoing stakeholder consultation on any future proposed changes to the structure of cost recovery fees. |
| *Access to quality use of the PBS listed medicines and NIP listed vaccines* | |
| Stakeholders commented on the need for an appropriate cost recovery fee structure. Support was expressed for the existing fee structure which contributes to ensuring continuity of public access to cost-effective and affordable medicines listed on the PBS and vaccines listed on the NIP. | The Department remains committed to timely and affordable access to medicines listed on the PBS and vaccines listed on the NIP. The Department conducts an annual review of the activity-based cost model inputs to ensure the model and associated fees remains contemporary. Further, a recent independent review of the activity-based cost model found that the model remains appropriately structured and fit for purpose. Additionally, as a result of the independent review, the Department is conducting a time and motion study to review the full list of tasks accounted for in the cost model that make up the PBAC submission process to ensure that this list reflects current administrative processes. |
| *Fee waivers and exemptions* | |
| Stakeholders requested more than one opportunity to seek fee exemptions for submissions relating to the listing of TGA designated orphan medicines. | Under current arrangements, applicants may seek a fee exemption if the submission relates to a designated orphan drug and it is the first time that the PBAC has considered the drug.  The Department does not currently have any plans to review and amend the existing fee exemption criteria.  Sponsors are reminded that fee waiver requests also remain applicable to all submission types, including for those submissions seeking the PBAC consideration a second or greater time. Fee waiver decisions are made by a delegate of the Department’s Secretary. The delegate will consider the financial viability and public interest of the submission, including whether the drug or vaccine will be used:   * for palliative care; or * as a paediatric medicine; or * for medical treatment of Aboriginal or Torres Strait Islander peoples.   Additional information regarding orphan drug fee exemptions and fee waiver requests can be found on the [PBS cost recovery webpage](https://www.pbs.gov.au/info/industry/listing/elements/fees-and-charges#Fee-waivers). |
| *Application of fees* | |
| Stakeholders expressed support of the fee waiver and fee exemption processes and policies currently in place.  Additional stakeholder comments sought consultation and further consideration of waiver provisions and alternative fee structures for lower value medicines and vaccines or for smaller companies. Examples proposed include:   * a risk-share approach to fees for lower revenue medicines and vaccines e.g., half the fee charged up front, with the remaining either charged once the projected revenue is reached or waived if revenue is lower than projected; or * a phased payment plan for smaller companies; or * a fee structure based on the expected revenue for an individual product. | The Department appreciates and notes stakeholder feedback on this matter. This feedback may be considered for future changes to cost recovery arrangements.  Current cost recovery policy arrangements require fees to be paid upfront and in full. This policy is in place to ensure that payments are received for the services provided by the Department to applicants prior to the PBAC consideration. This ensures that the Department does not expend additional resourcing on debt management activities.  Additionally, if an applicant’s request for services is withdrawn within the legislated withdrawal period, a full refund is provided, less the administrative deposit amount.  Finally, existing fee waiver and fee exemption provisions remain in place to provide equitable access to the PBAC submission processes. |
| *Independent review of the PBS cost recovery model* | |
| Stakeholders sought an update on progress and expected timeframe of the time and motion study currently being undertaken by the Department.  Stakeholders also noted the importance of consultation on the outcomes of the time and motion study prior to any changes coming into effect. | The Department is currently conducting a time and motion study reviewing the processes involved in PBAC submissions. This review is occurring as a result of a recently conducted independent review of the PBS activity-based cost model.  The Department commenced work on the time and motion study prior to the submission of applications for consideration at the March 2023 PBAC Meeting. As this PBAC cycle concludes, a significant portion of timings have been collected. The Department will continue to collect timings related to PBAC submissions through to the conclusion of the July 2023 PBAC cycle.  Additional timings are necessary to collect, particularly those related to resubmission pathways, to ensure a sufficient sample size exists to refresh the data in the cost model.  Once all relevant timings are collected at the conclusion of the July 2023 PBAC cycle, the time and motion study will shift away from PBAC submissions and begin assessment of the tasks and timings that make up the pricing and list management application processes.  The outcomes of this study will ensure that PBS cost recovery continues to remain consistent with the Australian Government Charging Framework, and that fees continue to accurately reflect the minimum efficient costs that the Department incurs in performing PBS evaluation and listing activities. The data obtained by the study will directly inform any required revisions to submission fees.  Depending on the magnitude of any changes to fees and administrative processes, Australian Government agreement to changes may be required. If this is the case, changes would likely occur via the 2024-25 Budget process.  The Department will continue to consult with industry on the outcomes of the study. Additional public consultation on the outcomes of the study will occur via the Cost Recovery Implementation Statement. |
| Stakeholders requested an update on the status of the other recommendations (other than the time and motion study outcomes) of the Independent Review. | As noted in section 3.2.2 of the CRIS, the Independent Review provided four primary recommendations, three of which have already been completed.   1. Confirm that the PBAC cost model will be reviewed and updated (as necessary) as proposed in 2022-23, including cost model documentation and supporting documentation (i.e., user guides); 2. Ensure that mechanisms are in place so that where prices are set using an indexation mechanism, that they are also reflective of minimum efficient costs; 3. Commit, publicly, to undertake a full cost model refresh during the 2022-23 financial year, with outcomes to be reflected in 2023-24 prices, except where legislative or policy issues are identified and further Government consideration may be required; 4. Consider whether the PBS CRIS adequately documents the stakeholder engagement strategy including a summary of the latest engagement round – who was consulted and when, what their views were, and whether/how these views have been considered. Better practice would also identify planned consultation processes and mechanisms to be used to seek stakeholder feedback.   Recommendations 1, 2 and 4 from the Independent review have been implemented. Recommendation 3, relating to the time and motion study, is the only remaining recommendation to be completed. |
| Stakeholders requested further review of cost recovery fees, noting that the scope of the Independent Review was limited to the PBS cost model and a broader independent audit is still required of the fees. | Clause 6.9.2 of the publicly available 2022 Strategic Agreement with Medicines Australia states the ‘Commonwealth will engage an independent entity to undertake a review during 2022 of the PBS activity-based cost model to assess the appropriateness of the list of cost recovered activities in the administration of the PBS and the cost allocations to them having regard to the Australian Government Charging Framework and Australian Government Cost Recovery Guidelines.’ The independent reviewer completed a robust review of the activity-based cost model in July 2022.  The Department notes the stakeholder feedback and clarifies that the cost recovery fees are solely calculated via the use of an activity-based cost model. The activity-based cost model collates all inputs and assumptions that form the cost base of the PBS evaluation and listing services provided to applicants. The cost model then distils these inputs into a final fee for each submission category, reflective of the minimum efficient costs incurred by the Department in the provision of these services to applicants.  The cost model was reviewed and deemed fit for purpose by the independent reviewer. The completion of the independent review has consequently fulfilled clause 6.9.2 of the 2022 Strategic Agreement. |
| *PBS improvements* | |
| Stakeholders sought commitment from the Department to ongoing consultation on PBS Process Improvements and any additional activities that may be considered for cost recovery purposes. | The Department remains committed to ongoing consultation with the medicines industry to ensure timely and appropriate access to new medicines and the ongoing viability of the PBS and NIP through PBS process improvements. The Department is committed to long term, constructive, working relationships with its stakeholders, particularly via the Access to Medicines Working Group (AMWG). The Strategic Agreement with Medicines Australia provides a platform of long term working arrangements and demonstrates the commitment the Department has to consulting with relevant stakeholders. |
| Stakeholders requested the development of a publicly available metric that reflects improvements in transparency and efficiencies of resources regarding PBS evaluation and listing process. | The Department would welcome discussion of the potential development of new metrics ([beyond the currently publicly available metrics already published on the PBS website](https://www.pbs.gov.au/info/general/pbs-process-improvements)) via the AMWG and any related subgroups. |
| *Resource allocation relating to cost recovery fees* | |
| Stakeholders requested that the CRIS document articulate, in a transparent manner, how the cost recovery fees are used with regard to resources and staffing at the Department. Publicly available metrics that reflect improvements in the transparency and efficiencies of resources directed to the PBS listing process should be developed in consultation with industry stakeholders. | The Department notes that table of 8 of this CRIS contains a breakdown of the unit costs associated with the performance of each activity for the 2023-24 financial year. Section 3.2.1 of this CRIS also details a number of specific cost drivers impacting these fee changes.  The Department notes, as per table 10, that the cost recovered revenue for 2023-24 is anticipated to be $32.06m, while the costs of providing these services to applicants is anticipated to be $39.70m, representing a deficit of $7.65m.  The revenue received from PBS/NIP cost recovery is collected by the Commonwealth as part of consolidated revenue. Appropriation is then provided to the Department to fund PBS/NIP evaluation and listing processes. |

1. The Australian Government Charging Framework and the CRGs are available on the [Department of Finance website](https://www.finance.gov.au). [↑](#footnote-ref-1)
2. Definition of the direct and indirect costs are from [the CRGs](https://www.finance.gov.au/sites/default/files/australian-government-cost-recovery-guidelines_0.pdf). [↑](#footnote-ref-2)
3. The Notice of Intent fee is payable in addition to the fees specified in the table above and as from 1 August 2022 apply to ATAGI submissions. [↑](#footnote-ref-3)
4. The Category 1 evaluation fee in table above applies to all submissions that meet the Category 1 criteria including instances where multiple submissions are lodged at the same time. [↑](#footnote-ref-4)
5. The Facilitated Resolution Pathway fee includes the workshop fee. This workshop fee is included in the non‑refundable deposit amount. [↑](#footnote-ref-5)
6. These fees include the five-year rebate management fee of $8,640. The rebate management fee line has no volumes on its own. [↑](#footnote-ref-6)
7. Any submissions requesting a fee waiver or fee exemption will be invoiced within 15 business days after the Department has received an application and a fee waiver or fee exemption has not been granted. [↑](#footnote-ref-7)
8. Pathway A, D, Secretariat Pathway – invoice is to be paid in full; if Pathway B or C selected – sponsor is invoiced the Pathway C (existing deed) fee and an adjustment can be made (if needed) once the final pricing agreement is reached. Cost recovery fee points are underlined.

   Note: Pricing Pathways A, B and C and the Deed Renewal fees include the five-year rebate management fee. [↑](#footnote-ref-8)
9. The cumulative balance includes a deficit of -$29.78 million from years prior to 2023-24. [↑](#footnote-ref-9)
10. As outlined in the [Department of Health’s Annual Report](https://www.health.gov.au/about-us/corporate-reporting/annual-reports). [↑](#footnote-ref-10)