Australian Government
Department of Health, Disability and Ageing

COST RECOVERY IMPLEMENTATION STATEMENT

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

1 July 2025 to 30 June 2026

Version 1.1

Charging for regulatory activity involves Government entities charging individuals or organisations in the non-government sector some or all of the minimum efficient costs of a specific Government activity. The Cost Recovery Policy along with the Australian Government Charging Framework sets out the policy under which Government entities design, implement and review charging for regulatory activities. The CRIS is the public document to ensure the transparency and accountability for the level of the charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

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1. INTRODUCTION

1.1. Purpose

This Cost Recovery Implementation Statement (CRIS) provides information on how the Department of Health, Disability and Ageing (the Department) implements cost recovery charging 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.

It reports actual financial and non-financial performance information for cost recoverable activities related to the listing and management of products included on the PBS and NIP and contains financial and demand forecasts for 2025-26 and three forward years. The Department will maintain the CRIS while the regulatory activity, or cost recovery for the activity, continues.

1.2. Description of the regulatory charging activity

1.2.1. What is the regulatory activity being cost recovered?

The Department provides a range of evaluation, listing and management services for the PBS and NIP that have been cost recovered since January 2010. In 2015, the Australian Government Charging Framework and the Cost Recovery Guidelines (now referred to as the Cost Recovery Policy) were introduced.

In July 2019 a revised cost model, aligned with the Australian Government Charging Framework, was introduced. The revised model included updated activities associated with a range of PBS process improvements (Stage 1) and reflected the efficient costs of providing PBS/NIP evaluation, listing and management services to industry.

In July 2020, an updated cost model was introduced with additional activities for revised submission categories and new resubmission pathways as part of implementing Stage 2 PBS process improvements on 1 January 2021. Fees were also updated to reflect contemporary IT depreciation costs, salary, and wage costs, consistent with whole-of-Government requirements.

In July 2023, the cost model was updated with new activities for Ministerial Determination requests (Stockholding), and changes to activities for Ministerial Discretion requests for Statutory Price Reductions (SPRs).

Fees charged only recover the costs of services directly requested by sponsors. Costs are not recovered for fee waivers and regulatory activities not directly attributed to an individual sponsor, such as maintaining the currency of medicine information and ensuring prices are compliant with legislation.

The 2025-26 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
- Independent reviews

ATAGI pre-submission advice

ATAGI advises the Minister for Health and Ageing (the Minister) on the NIP and other immunisation issues. The *National Health Act 1953* requires a positive recommendation from the PBAC before vaccines may be listed on the NIP. ATAGI has been providing pre-submission advice to vaccine applicants and evaluation advice to the PBAC since 2006.

ATAGI cost recovered activities include providing advice to support PBAC evaluations of vaccines for the NIP, including on clinical, technical and implementation matters. Fees for this service were introduced in 2020.

PBAC Pre-submission Meetings and Submission Services

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 recovered activities include pre-submission advice provided by the Department to assist sponsors in developing a PBAC submission and evaluation activity to support PBAC consideration of medicines for listing on the PBS. Fees for pre-submission meetings were introduced in 2019. Fees for evaluation activity to support PBAC consideration 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 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 introduced in 2019 for price change requests. Deed-related fees were introduced in 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).

1.2.2. What policy outcomes will the activity achieve?

The regulatory activity contributes to achieving Outcome 2 (Program 2.3) in the Health Portfolio Budget Statements.

Outcome 2: Individual Health Benefits

Ensuring improved access for all Australians to cost-effective and affordable medicines, medical, dental, and 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).

1.2.3. Why is charging appropriate for the regulatory activity?

Charging for evaluation, listing and management services for products on the PBS and NIP is appropriate because:

- Applicants seeking public reimbursement for medicines/vaccines usually derive a direct financial benefit from the services provided by Government.
- It improves the efficiency and equity with which Government services are provided.

- It sends price signals to individuals or groups about the cost or value of a Government activity.
- An identifiable group of parties produce the regulatory effort required to list their products on the PBS or NIP.
- It supports the quality use of PBS listed medicines and the ongoing sustainability of the PBS.

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, regulation, or a combination of these. The Cost Recovery Policy, sets 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.

1.2.4. Who will pay the regulatory charges?

The PBAC considers medicine/vaccine submissions from sponsors 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.

Applicants are charged fees for services provided. In certain circumstances, applicants may be exempt from paying cost recovered fees, or may request that fees are waived where an application is financially unviable, and it is in the public interest. This ensures cost recovery is not a barrier to accessing medicines/vaccines in Australia.

2. POLICY AND STATUTORY AUTHORITY TO CHARGE (COST RECOVER)

2.1. Government policy approval to charge for this regulatory activity

2.1.1. 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 Stage 1 PBS process improvements and related cost recovery including annual indexation of fees in line with the Australian Government Charging Framework. Existing fees were also revised to reflect the efficient costs of services provided to industry during the 2019 PBS listing process. Following stakeholder feedback and to reduce the impact on applicants, Government agreed to the phased increase of existing fees (50 per cent in July 2019 with the remaining 50 per cent in July 2020).

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

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.

The Government has not announced any significant policy changes affecting PBS/NIP cost recovery for 2025-26.

PBS post listing regulatory activities undertaken but not charged

Consultation with industry in early 2018 included a proposal to charge for PBS post listing activities where the work undertaken cannot be directly attributed to an individual sponsor. 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 a medicine's price is compliant with legislation ensure the ongoing clinical and cost effectiveness of PBS medicines and Australian patients' ongoing access to medicines. These activities benefit 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 (2018-19 estimate). 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 Government did not proceed with a PBS listing levy and the costs for post listing regulatory activities are not recovered. This partial cost recovery approach will continue to be reviewed as required under the Australian Government Charging Framework.

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* (the Regulations) provide authority for cost recovery charges for services provided to list and manage items on the PBS/NIP.

2.2.1. Legislative amendments

Cost recovery regulations

On 1 July 2025 the Regulations were amended to include fee changes for 2025-26.

The Regulations can be accessed via the PBS website or on the Federal Register of Legislation.

3. CHARGING (COST RECOVERY) MODEL

3.1. Outputs and business processes of the activity

The cost recovery fee categories are:

- *Section 3.1.1– ATAGI pre-submission advice (evaluation)*
- *Section 3.1.2 – PBAC pre-submission meetings*
- *Section 3.1.3 – Submission Services, including Notice of Intent*
- *Section 3.1.4 – Pricing Services, including Notice of Intent for Pricing*
- *Section 3.1.5 – PBS List Management Services.*

Activity descriptions are detailed in Tables 1-5, with cost breakdowns in Table 8.

3.1.1. ATAGI pre-submission advice (evaluations)

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.

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.

A Notice of Intent step for ATAGI applications 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 in Table 1.

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 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 when an applicant has requested a meeting.

There are two types of pre-submission meetings, as outlined in Table 2.

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 allows the Department time to plan, prepare and resource all incoming identified assessments, to support efficiency and provide certainty for submissions progressing to PBAC.

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 in Table 3 (Initial Submissions) and Table 4 (Re-Submission).

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.

Submission Fee Category	Description

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. Category 1 submissions will be considered by the ESC and may include DUSC 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 requesting 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. Category 2 submissions will be considered by the ESC and may include DUSC 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

Submission Fee Category	Description
	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.

Table 4 - PBAC submission activity description (Re-Submissions)

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.

Resubmission Fee Category	Description
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 plan, 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 PBAC recommendation, 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 in Table 5.

Table 5 - 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.

Fee Category	Description
	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 a 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 in Table 6.

Table 6 - PBS List Management requested activities description

Fee Category	Description
Price increase request (including brand premiums)	Applicants may ask the Minister (or delegate) to consider a request for a price increase for a particular product listed on the PBS.
Ministerial discretion request	Applicants may ask the Minister (or delegate) to 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.

Fee Category	Description
Deed variation request	Applicants may seek to vary the terms of an existing deed (within the current deed term). Activities include negotiating potential deed variations under s85E of the *National Health Act 1953.*
Ministerial determination request (Stockholding request)	Applicants may request a determination by 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 activity

3.2.1. Outcome of annual review of cost recovery arrangements for 1 July 2025

The Department reviews PBS/NIP evaluation, listing and management fees annually. The activity based costing methodology agreed with the Department of Finance remains the basis for charging. Indexation is applied to all fees to reflect the current minimum efficient costs of delivering the services. This approach is consistent with other cost recovery arrangements across the Department.

The annual review for the 2025-26 financial year has resulted in an increase to fees. On average, fees for PBS services have increased by 1.90% (ranging from 1.22% to 2.85%) compared to fees charged in the 2024-25 financial year. ATAGI fees have also increased by 2.95% compared to fees charged in the 2024-25 financial year.

The Department is currently undertaking a review of the PBAC activity based charging model cost base to update the business processes and staff effort involved in the administration of submissions. Outcomes of the ongoing review will be reflected in fees as they become available.

3.2.2. Fees and costs from the activity based costing model

In line with the Australian Government Charging Framework, the following costs[1] are included in the activity based costing model:

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). Direct costs also include the ongoing IT maintenance costs of the Health Products Portal (HPP), consistent with the Australian Government Charging Framework.

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.

[1] Definitions of the direct and indirect costs are from the Australian Government Charging Framework.

Table 7 - Unit cost per activity with breakdown for 2025-26

Estimated Unit Cost per Activity 2025-26	Direct Costs	Indirect Costs	Capital	Total unit cost
ATAGI Pre-submission Evaluation				
Complex Submission	218,327	1,999	-	220,326
Simple Submission	119,949	1,357	-	121,306
Pre-Submission Meetings				
1st Pre-Submission Meeting	14,252	2,229	211	16,692
2nd Pre-Submission Meeting	19,421	3,005	283	22,710
Intent to Apply Submissions				
Intent to Apply/Notice of Intent	392	66	6	464
Submission Services (PBAC Evaluation)				
Category 1	251,486	16,754	1,608	269,849
Category 2	199,377	9,992	968	210,337
Category 3	40,437	4,845	470	45,751
Category 4	30,483	4,622	449	35,554
Resubmission - Early re-entry	38,756	5,013	485	44,253
Resubmission - Early resolution	38,887	5,035	487	44,408
Resubmission - Facilitated resolution pathway	274,752	11,799	1,129	287,680
Resubmission - Standard re-entry	196,970	10,060	973	208,004
Secretariat Submission	10,476	1,827	177	12,480
Generic Submission	5,830	999	96	6,925
PBS Pricing Services				
Pricing Pathway A	120,418	19,410	1,868	141,696
Pricing Pathway B	93,905	14,964	1,439	110,308
Pricing Pathway C	59,590	9,362	902	69,854
Pricing Pathway D	17,924	2,991	288	21,203
Pricing Secretariat	10,937	1,840	178	12,954
PBS List Management Services				
Deed Variations	2,095	15	-	2,111
Deed Renewals	2,259	51	-	2,310
Price Increases	4,529	763	73	5,366
Ministerial Discretion Request	6,377	996	94	7,467
Stockholding Request	4,496	705	67	5,268
Rebate Management Service Fee	7,179	2,020	-	9,200

Pricing Pathways A, B, C, and Deed Renewal unit costs in Table 7 exclude Rebate Management Service costs.

The Rebate Management Service Fee costs listed in Table 7 represent costs for 5 years of service.

3.3. Design of the regulatory charge

For the 2025-26 financial year, the total regulatory effort required by the Department to deliver services related to PBS and NIP listing activities is estimated to be $42.46 million.

The Regulations provide for fee exemptions and waivers in certain circumstances. These are available across all charging categories, except for pre-submission meetings. The estimated cost for waivers and exemptions granted in 2025-26 is $2.86 million, which is not recovered.

PBS post listing regulatory activities (see Section 2.1) are estimated to cost $5.76 million, which is not recovered.

Table 8 details the cost recovery fees and revenue estimates for 2025-26, including waivers and exemptions.

Table 8 - PBS cost recovery activity and cost summary for 2025-26

Activity	Estimated Volume	Estimated Cost ($m)	Estimated Waivers/ exemption Costs ($m)	Post Listing activities not recovered ($m)
ATAGI pre-submission evaluation	6	$ 1.02	$ -	
Pre-submission meetings	70	$ 1.23	$ -	
Intent to apply/notice of Intent	293	$ 0.14	$ -	
PBAC Submission evaluation	361	$ 26.53	$ 1.96	
Positive recommendation pathways	81	$ 4.35	$ 0.75	
PBS list management activities	639	$ 3.42	$ 0.15	
PBS list regulatory activities	5350	$ 5.76	$ -	$ 5.76
Total		**$ 42.46**	**$ 2.86**	**$ 5.76**

With consideration to revenue forgone due to waivers and exemptions, the total revenue is estimated to be $34.30 million.

Table 9 details the cost recovery fees, including volume and revenue estimates for 2025-26. Table 9 includes the proposed cost recovery fees from 1 July 2025 to 30 June 26, subject to Ministerial approval.

In addition, there is an Independent Review fee, based on the charging approach used for the Category 2 evaluation fee. No independent review applications have been submitted in the past five years, and there is no revenue estimated for this category.

Table 9 - Proposed 2025-26 cost recovery fees and estimated volumes, cost and revenue for 2025-26

Charging Category	Type	Unit cost	Unit price	Estimated volumes of Applications to be Invoiced	Estimated total cost ($million)	Estimated total revenue ($million)
Complex Submission	Fee	$ 220,326	$ 220,330	3	$ 0.66	$ 0.66
Simple Submission	Fee	$ 121,306	$ 121,310	3	$ 0.36	$ 0.36
Pre-Submission Meetings						
1st Pre-Submission Meeting	Fee	$ 16,692	$ 16,690	60	$ 1.00	$ 1.00
2nd Pre-Submission Meeting	Fee	$ 22,710	$ 22,710	10	$ 0.23	$ 0.23
Intent to Apply Submissions						
Intent to Apply/Notice of Intent	Fee	$ 464	$ 465	293	$ 0.14	$ 0.14
PBAC Evaluation						
Category 1	Fee	$ 269,849	$ 269,850	15	$ 4.05	$ 4.05
Category 2	Fee	$ 210,337	$ 210,340	48	$ 10.10	$ 10.10
Category 3	Fee	$ 45,751	$ 45,750	34	$ 1.56	$ 1.56
Category 4	Fee	$ 35,554	$ 35,550	32	$ 1.14	$ 1.14
Resubmission - Standard re-entry	Fee	$ 208,004	$ 208,000	24	$ 4.99	$ 4.99
Resubmission - Facilitated resolution pathway	Fee	$ 287,680	$ 287,680	2	$ 0.58	$ 0.58
Resubmission - Early resolution	Fee	$ 44,408	$ 44,410	5	$ 0.22	$ 0.22
Resubmission - Early re-entry	Fee	$ 44,253	$ 44,250	18	$ 0.80	$ 0.80
Secretariat Submission	Fee	$ 12,480	$ 12,480	6	$ 0.07	$ 0.07
Generic Submission	Fee	$ 6,925	$ 6,930	155	$ 1.07	$ 1.07
Positive Recommendation pathways						
Pricing Pathway A	Fee	$ 141,696	$ 150,900	5	$ 0.71	$ 0.75
Pricing Pathway B	Fee	$ 110,308	$ 119,510	8	$ 0.88	$ 0.96
Pricing Pathway C	Fee	$ 69,854	$ 79,050	19	$ 1.33	$ 1.50
Pricing Pathway D	Fee	$ 21,203	$ 21,200	26	$ 0.55	$ 0.55
Pricing Secretariat	Fee	$ 12,954	$ 12,950	6	$ 0.08	$ 0.08
Other Chargeable activities						
Deed Variations	Fee	$ 2,111	$ 2,110	6	$ 0.01	$ 0.01
Deed Renewals	Fee	$ 2,310	$ 11,510	30	$ 0.07	$ 0.35
Price Increases	Fee	$ 5,366	$ 5,370	369	$ 1.98	$ 1.98
Ministerial Discretion Request	Fee	$ 7,467	$ 7,470	26	$ 0.19	$ 0.19
Ministerial determination (stockholding) reques	Fee	$ 5,268	$ 5,270	182	$ 0.96	$ 0.96
Rebate Management Service Fee	Fee	$ 1,840	$ 9,200	62	$ 0.11	
					$ 33.84	$ 34.30

Rebate Management Service Fee is included in the prices for Pricing Pathways A, B , C, and Deed Renewals.

The price for the Rebate Management Service Fee includes services for 5 years. Therefore, estimated revenue includes 4 years of Rebate Management Service Fees in advance.

Table 10 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 10 - 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[2]
	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 Point[1]
	Pricing offer made
	Pricing agreement reached
	Adjustment to the invoicing based on the pricing agreement reached[3]
	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

[2] 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.

[3] 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.

Category	ATAGI Pre-submission Evaluation Process
	Post Listing Fee Point
	Actioning the requested post listing activity

Please refer to **Stage 2 – Develop charging model** of RMG-302 Implementing the Charging Framework.

4. RISK ASSESSMENT

A Charging Risk Assessment (CRA) was conducted in February 2025. The overall risk rating is 'low' due to some fees increasing by <5% (average increase 1.9%). All implementation risks considered as part of the CRA were assessed as low risk, including the change in total annual revenue, if legislative changes are required, and if consultation occurred.

5. STAKEHOLDER ENGAGEMENT

Application fees may be charged for services provided to the sponsors of medicines seeking to be listed on the PBS, or vaccines to be listed on the NIP. Pharmaceutical industry applicants usually derive a direct financial benefit from the services provided by Government.

Annual consultation occurs through the publishing of a draft CRIS. Public consultation was undertaken from 29 January to 13 February 2025 to seek stakeholder feedback on the 2025-26 CRIS. Four submissions were received, and a summary of the feedback and departmental responses is at **Attachment A.**

The Department's stakeholder engagement strategy for PBS/NIP cost recovery arrangements includes regular, transparent, and timely consultation with pharmaceutical industry stakeholders via the Access to Medicines Working Group (AMWG) and other established governance mechanisms under the Strategic Agreements with the medicines industry.

6. FINANCIAL PERFORMANCE

6.1. Financial Estimates

The forecast expenses and estimated revenue of the partial cost recovery arrangements for the 2025-26 financial year and three forward years are in Table 11.

There is an ongoing net deficit, which is supplemented by Government appropriation to the Department for 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 11 - Financial estimates for PBAC cost recovery activities for 2025-26 and three forward years

Financial estimates	2025-26 ($million)	2026-27 ($million)	2027-28 ($million)	2028-29 ($million)
Total Revenue	$ 34.30	$ 35.15	$ 35.62	$ 36.25
Total expenses	$ 42.46	$ 43.53	$ 44.14	$ 44.95
Balance (revenue less expense)	-$ 8.16	-$ 8.38	-$ 8.52	-$ 8.70
Cumulative balance	-$ 64.17	-$ 72.55	-$ 81.07	-$ 89.77

Financial estimates	2025-26 ($million)	2026-27 ($million)	2027-28 ($million)	2028-29 ($million)
Balance management strategy explanation	The growing cumulative balance deficit reflects a continued forecast under recovery, primarily due to post listing activities, fee waivers and exemptions that are not cost recovered. This will continue to be monitored over time to ensure the degree of alignment between expenses and revenue is appropriate.			

6.2. Financial Outcomes

Table 12 is 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 4-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 12 - Financial performance for cost recovered activities

Financial Outcomes	2021-22 ($million)	2022-23 ($million)	2023-24 ($million)	2024-25 ($million)
Estimates				
Revenue (X)	$ 28.14	$ 27.84	$ 32.05	$ 33.62
Expenses (Y)	$ 35.62	$ 35.00	$ 39.70	$ 41.59
Balance (X-Y)	-$ 7.48	-$ 7.16	-$ 7.65	-$ 7.97
Actuals				
Revenue = Y	$ 26.90	$ 26.95	$ 26.81	$ 29.72
Expenses = X	$ 31.76	$ 32.88	$ 39.01	$ 43.75
Balance = Y-X (Negative deficit)	-$ 4.86	-$ 5.93	-$ 12.20	-$ 14.03
Cumulative balance (Negative deficit)	-$ 23.85	-$ 29.78	-$ 41.98	-$ 56.01
Material variance explanation	The under-recovery is due to a combination of factors, including higher than forecast fee waivers and exemptions, and greater costs of post-listing services that are not recovered.			
Balance management strategy explanation	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.			

Table 13 details the depreciation of IT assets, including PharmCIS for 2025-26 and three forward years. In June 2025 Depreciation costs are proportionally attributable across a range of NIP/PBS cost recoverable activities.

Table 13 – Depreciation

Depreciation	2025-26 ($million)	2026-27 ($million)	2027-28 ($million)	2028-29 ($million)
Aggregate net book value - start of financial year	0.71	0.43	0.14	0.00
Aggregate accumulated Depreciation	9.01	9.30	9.58	9.72
Aggregate depreciation Expense	0.28	0.28	0.14	0.00

In the 2024-25 CRIS, table 13 contained depreciation information for both the HPP and PharmCIS. In 2025-26, and going forward, this table will contain information for PharmCIS and any other IT products that are deemed to be depreciable assets.

In 2023-24, the Department reviewed the application of AASB 116 Property, Plant, and Equipment, and AASB 138 Intangible Assets against the recognition and measurement of its internally developed computer software. As a result of this review, the HPP has been reclassified to a Software as a Service (SAAS) arrangement and costs will be expensed when they are incurred.

The costs incurred on an annual basis in utilising the SAAS arrangement for the HPP are greater than the depreciation expense that has been included in the cost base of the charging model which determine fees.

In 2025-26 the fees will not include costs for depreciation or the SAAS arrangement for the HPP.

A full review of the charging model is planned to be undertaken in 2025. The review will consider the costs to be included from the SAAS arrangement for the HPP from 2026-27 onwards, noting this is expected to include future costs associated with the continued build of the HPP. This will be subject to Government consideration.

7. 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[4], consistent with the PGPA Act. The performance requirements are:

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:

a) the extent and timeliness with which responsible persons are provided copies of documents relevant to their submission to the Pharmaceutical Benefits Advisory Committee
b) 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
c) the number of responsible persons seeking a review of the Pharmaceutical Benefits Advisory Committee recommendation.

[4] As outlined in the Department of Health, Disability and Ageing Annual Report

Table 14 - Ensuring access to cost-effective, high-quality, clinically effective medicines through the PBS

Percentage of new medicines recommended by the Pharmaceutical Benefits Advisory Committee that are listed on the Pharmaceutical Benefits Scheme within 6 months of in principle agreement to listing arrangements.					
Source: Department of Health, Disability and Ageing Annual Report 2024-25, p. 95.					
2024-25 Target	**2024-25**	**2023-24**	**2022-23**	**2021-22**	**2020-21**
≥80%	100%	100%	100%	100%	100%
	Result: Met				

Metrics to reflect PBS process improvements and target 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.

8. KEY FORWARD DATES AND EVENTS

Table 15 - KEY FORWARD DATES AND EVENTS

Activity	Date
Update CRIS for 2026-27	30 June 2026

9. CRIS APPROVAL AND CHANGE REGISTER

Table 16 - CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS change	CRIS change	Approver	Basis for change
30 November 2025	Update with 2024-25 actual financial and non-financial results	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2024-25 actual results
22 February 2025	Approval of 2025-26 CRIS	Minister for Health and Aged Care	Respond to stakeholder consultation feedback.
30 January 2025	Approval of draft 2025-26 CRIS for consultation	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS consultation including revised estimates
29 November 2024	Approval update to 2024-25 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2023-24 financial results
28 June 2024	Approval of 2024-25 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Respond to stakeholder consultation feedback.
27 March 2024	Approval of draft 2024-25 CRIS for consultation	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS consultation including revised estimates
29 November 2023	Approval update to 2023-24	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2022-23 financial results
1 July 2023	Approval of 2023-24 CRIS	Minister for Health and Aged Care	Further clarification following consultation feedback.
3 May 2023	Approval of draft 2023-24 CRIS for consultation	First Assistant Secretary, Technology Assessment and Access Division	Revised fees to reflect annual indexation in line with the Australian Government Charging Framework

Date of CRIS change	CRIS change	Approver	Basis for change
28 October 2022	Approval of updates to 2022-23 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Reporting on financial and non-financial performance for 2021-22.
1 August 2022	Approval of 2022-23 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Further clarification following consultation feedback.
15 June 2022	Approval of draft 2022-23 CRIS for consultation	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 of update to 2021-2022 CRIS	Technology Assessment and Access Division	References to the new National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022 updated.
30 November 2021	Approval of updates to 2021-2022 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Reporting on financial and non-financial performance for 2020-21.
21 June 2021	Approval of 2021-2022 CRIS	Acting First Assistant Secretary, Technology Assessment and Access Division	Further clarification on fees following consultation feedback.
9 April 2021	Approval of draft 2021-22 CRIS for consultation	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 of 2020-21 CRIS	Minister for Health	New regulatory charging activity and 2019-20 outcome statement
24 September 2020	Approval of draft 2020-21 CRIS for consultation	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 of 2020-21 CRIS	Acting Secretary for Health	Updated to reflect introduction of ATAGI fees (operational change)
9 December 2019	Approval of updates to 2019-20 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Reporting on financial performance for 2018-19
11 June 2019	Approval of 2019-20 CRIS	Minister for Health	Revalidation of the costing model – to reflect delay to ATAGI and deed management fees (policy change)
10 April 2019	Approval of 2019-20 CRIS	Minister for Finance and the Public Service	New regulatory charging activity
13 March 2019	Approval of 2019-20 CRIS	Minister for Health	New regulatory charging activity
7 March 2019	Certification of 2019-20 CRIS	Secretary for Health	To ensure compliance with Australian Government Cost Recovery Guidelines and Government

ATTACHMENT A – SUMMARY OF STAKEHOLDER CONSULTATION FEEDBACK ON THE DRAFT 2025-26 CRIS AND DEPARTMENT RESPONSES

Public consultation for the 2025-26 Draft CRIS occurred from 31 January to 13 February 2025. Four stakeholders of the medicines industry provided feedback, their comments as well as the responses from the Department have been detailed below.

Stakeholder Comments	Department Response
Fee changes for 2025-26	
Stakeholders raised concerns about the impact of year-on-year increases in cost recovery fees to the pharmaceutical industry. Earlier engagement on any future fee changes was also requested.	PBS/NIP cost recovery fees are calculated using an activity based cost model agreed with the department of Finance that reflects the minimum efficient costs to deliver the cost recoverable services. The primary driver of fee increases for 2025-26 is indexation, to commence on 1 July 2025. The Department notes no significant Government policy changes are affecting PBS/NIP cost recovery in 2025-26. The Department is committed to timely consultation with stakeholders including through established governance mechanisms with industry and the annual CRIS consultation process.
Impact of fee increases on sponsors of generic and biosimilar medicines	
Concerns were raised about the ongoing impact of increased cost recovery fees to patient safety and stability of the generic and biosimilar medicines industry. Suggestions included developing an alternative funding model for generic and biosimilar PBAC/PBS activities.	In 2025-26 cost recovery fees are increasing between 1.5% and 2.4% for generic and biosimilar submissions, ranging from $45,750 for a Category 3 PBAC evaluation for a biosimilar medicine, $6,930 for a generic submission and $2,110 for a Deed Variation. Fees are significantly lower than those for new PBS listings medicines (determined by the activity based cost model). All sponsors can request submission fees are waived where in the public interest and financially unviable. The Government's Strategic Agreements with the medicines industry include a range of incentives designed to manage supply chain risks and long-term sustainability. This includes additional investment in supply security, including floor price protection for low-cost medicines and other changes to statutory pricing arrangements. The Department continues to jointly monitor and manage the implementation of the Agreements with industry, to resolve issues that emerge and develop policy advice to Government.

Stakeholder Comments	Department Response
Changes to the Health Products Portal (HPP) – Software as a Service (SAAS)	
Stakeholders queried the reclassification of the HPP from an IT asset to software as a service and the potential impact on fees in 2026-27.	The Department acknowledges the queries on the reclassification of HPP and potential impact on future cost recovery fees. A full review of the PBS charging model will be undertaken in 2025 which will consider all costs associated with the HPP. Any material changes to the PBS cost recovery arrangements are subject to Government consideration through a Budget process.
Fee structures and payment arrangements	
Stakeholders sought a commitment from the Department to consult on any new cost-recovered activities. Some alternate fee structure and payment arrangements were suggested: • alternate fee structure for vaccines and orphan medicines to facilitate reimbursement of critical therapies. • 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.	The Department is committed to timely consultation with stakeholders including through established governance mechanisms with industry and the annual CRIS consultation process. Fees are generally paid upfront and in full. This approach aims to ensure that payments for departmental services are received before PBAC or ATAGI consideration. This minimises avoidable debt management activities that would otherwise not be cost recoverable. Sponsors of orphan drugs and vaccines of high public need may be eligible for fee exemptions or waivers if the criteria in Part 7 of the Regulations are met.
Fee waivers and exemptions	
There was general stakeholder support for the fee waiver and exemption arrangements to help provide equitable access to the PBAC process. Several alternate fee policies were also suggested: • Removal, or full exemption, of cost recovery fees for orphan-designated medicines. • General expansion of fee waiver provisions, including where there are multiple resubmissions.	Fee exemption and waiver arrangements ensure cost recovery is not a barrier to accessing health technologies and services in Australia. Applicants may be exempt from fees for submission services in certain circumstances, e.g. if the application relates to a TGA designated orphan drug and it is the first time that the PBAC has considered the drug. Fee waiver requests are available to all submission types, including for those submissions seeking the PBAC consideration a second or subsequent time. The department delegate must consider the request against legislated public interest criteria including its financial viability. The Department notes the stakeholder feedback and continues to monitor the suitability of the current fee exemption and waiver arrangements.

Stakeholder Comments	Department Response
HTA Policy and Methods Review Implementation	
Stakeholders sought a commitment from the department to ongoing consultation on PBS process improvements and any additional activities that may be considered for cost-recovery purposes, including reforms recommended as part of the HTA Policy and Methods review.	The Department acknowledges the interest of stakeholders in the outcomes of the HTA Policy and Methods Review (HTA Review). The Department is committed to ongoing consultation with stakeholders including the medicines industry and will continue to support reforms including any Government responses resulting from the HTA Review.
Cost recovery levy	
Remove references in section 2.1 to a previous Government decision not to introduce a PBS listing levy.	The information at section 2.1 is factual and reflects the outcomes of past consultation and current Government policy, including the Australian Government Charging Framework requirement to continue to review this partial cost recovery approach. The Department remains committed to ongoing consultation with the pharmaceutical sector on PBS/NIP cost recovery arrangements.