
Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme

(including consideration of vaccines for the
National Immunisation Program)

Version 2.6



Australian Government

**Department of Health
and Aged Care**

Title: Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme

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Contents

Contents iii

Shortened forms and definitions	vii
Acronyms and abbreviations.....	vii
Definitions	vii
1 Purpose	1
1.1 Purpose of this document.....	1
1.2 Cost recovery	1
2 Listing process	3
3 Confidentiality and transparency.....	4
3.1 Managing and assessing confidential material.....	4
3.2 Managing conflicts of interest	6
3.3 Managing outcomes processes transparently	6
4 Pre-submission requirements.....	8
4.1 Types of submissions	8
4.2 Guidelines for preparing submissions.....	12
4.3 Timeframes for the PBS	12
4.4 Pre-submission meetings.....	13
4.5 Integrated codependent submissions	17
5 Lodging submissions for listing medicines or vaccines	18
5.1 Intent to Apply	18
5.2 Lodging a submission	18
5.3 Compliance with standard IT capability.....	18
5.4 Category 1 and Category 2 submissions	19
5.5 Category 3 and Category 4 submissions	20
5.6 Committee secretariat submissions.....	21
5.7 Reconsideration of a Recommendation	21
5.8 New brand of existing pharmaceutical item submissions (not requiring PBAC consideration)	21
5.9 Providing documents after lodging a submission.....	22
6 Procedures for consideration of submissions	23
6.1 PBAC subcommittees.....	23
6.2 Evaluation of submissions.....	25
6.3 Management of parallel process submissions.....	25
6.4 Input of the applicant into the PBAC consideration	26
6.5 Role of the Australian Technical Advisory Group on Immunisation for requests to list vaccines.....	28

6.6	Role of the Nutritional Products Working Party	29
6.7	Consumer input.....	30
6.8	Additional clinical input	31
6.9	PBAC and subcommittee members attending other meetings	32
6.10	Stakeholder meetings	32
6.11	Codependent submission processes.....	34
7	Post-PBAC procedures for applicants	35
7.1	Notification of outcomes of PBAC	35
7.2	Independent review.....	36
7.3	PBAC Outcomes	36
7.4	Public Summary Documents	37
8	Procedures for a positive recommendation to list	43
8.1	Pricing pathways	45
8.2	Notice of Intent for Pricing	47
8.3	Pricing offer package.....	47
8.4	Negotiation and agreement.....	48
8.5	Finalisation of the budget impact	49
8.6	Finalisation of restriction wording.....	50
8.7	Preparation and finalisation of additional access arrangements	51
8.8	Other listing documents required.....	52
8.9	Notification of listing on the PBS	53
8.10	Listing a vaccine on the NIP	53
9	Procedures for submissions not recommended	55
9.1	Resubmission pathways.....	55
9.2	Intent to Apply – resubmission pathways	58
9.3	Lodging a submission for a resubmission pathway	59
9.4	Facilitated Resolution Workshop.....	60
9.5	Resubmission requirements and procedures for consideration of resubmissions	61
9.6	Post-PBAC procedures for applicants	62
10	Review of PBS listings	63
10.1	Drug Utilisation Sub-Committee review	63
10.2	Post-market Reviews	64
10.3	PBAC requested research report	65
	Appendix A Information sources and contacts	66
A.1	Online information.....	66
A.2	Departmental contact details	66
	Appendix B – Supporting guidance for PSDs.....	70

Record of updates

Date	Version	Summary of changes
October 2016	Version 1.0	Procedure guidance released.
September 2017	Version 1.1	Updated parallel process guidance at 6.3 and Department of Health Branch and Division names
January 2018	Version 1.2	Updated Procedures for consideration of submissions at 6.6 Role of the Nutritional Products Working Party
September 2018	Version 1.3	Updated parallel processing of a biosimilar medicine at 6.3 Management of parallel process submissions
February 2019	Version 1.4	Updated documentation requirements at 5.7 New brand of existing pharmaceutical item submissions (not requiring PBAC consideration). Updated contact information at A.2.6 Matters relating to confirming the price and other post-PBAC recommendation matters.
June 2019	Version 1.5	Updated documentation requirements at 5.8 New brand of existing pharmaceutical item submissions (not requiring PBAC consideration). Updated contact information at A.2.6 Matters relating to confirming the price and other post-PBAC recommendation matters.
October 2019	Version 1.6	Updated procedures at: 2. Listing process, 4.4 Cost Recovery, 4.5 Pre-submission meetings, 8. Procedures for a positive recommendation to list. Updated document to include 5.1 Intent to Apply form. Updated contact information at A.2.2 Matters related to pre-submission meetings and post-PBAC meetings with the Chair.
April 2020	Version 1.7	Updated procedures at: 7.4 Public Summary Documents
June 2020	Version 1.8	Added Definitions, updated references to 'days' and timelines and other minor updates for clarification across the document. Updated procedures at: 2. Listing process, 3.1.1 Material contained in submissions, 4.3.2 Timeframes for integrated codependent submissions, 5. Lodging submissions for listing medicines or vaccines including 5.1 Intent to Apply form, 6.5 Role of the Australian Technical Advisory Group on Immunisation for requests to list vaccines, 7.4 Public Summary Documents. Updated document to include 3.3.6 Medicine Status Website and Appendix B.
July 2020	Version 1.9	Updated procedures at: 7.4 Public Summary Documents
November 2020	Version 1.10	Updated procedures at: 5.7 New brand of existing pharmaceutical item submissions (not requiring PBAC consideration)
December 2020	Version 2.0	Added definition and updated Section 1. Purpose. Updated procedures to reflect the introduction of Stage 2 PBS process improvements including revised submission categories and new resubmission pathways includes changes to processes at 2. Listing process, 3. Confidentiality and transparency, 4. Pre-submission requirements, 5. Lodging submissions for listing medicines or vaccines, 6. Procedures for consideration of submissions, 7. Post-PBAC procedures for applicants, 8. Procedures for a positive recommendation to list and the addition of a new 'Section 9 – Procedures for submissions not recommended'. Updated contact details at Appendix A.2
September 2021	Version 2.1	Updated requirements under Criterion 2 at: 7.4 Public Summary Documents and Appendix B
October 2021	Version 2.2	Updated Section 5.8 New brand of existing pharmaceutical item submissions (not requiring PBAC consideration) to provide guidance for applications to list new brands on the Repatriation Pharmaceutical Benefits Scheme.
December 2021	Version 2.3	Updated Section 8.9 Notification of listing on the PBS
April 2022	Version 2.4	Updated procedures at: 4.1.3 Category 3 submissions, 4.1.4 Category 4 submissions, 4.1.6 Application for a new brand or new oral form of an existing pharmaceutical item, 5.5 Category 3 and Category 4

Date	Version	Summary of changes
		submissions, 5.8 New brand or new oral form of existing pharmaceutical item submissions (not requiring PBAC consideration), 6.3 Management of parallel process submissions, and 9.1 Resubmission Pathways. References to remade <i>National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022</i> updated throughout the procedure guidance.
December 2022	Version 2.5	Updated procedure at: 7.4.3 Timeframe for Public Summary Document publication. Name of the Department of Health and Aged Care updated throughout the procedure guidance.
September 2025	Version 2.6	Updated wording at 6.1.3 Role of the Drug Utilisation Sub-Committee. Wording was changed from “ <i>DUSC considers all Category 1 and a selection of Category 2 submissions to the PBAC</i> ” to “ <i>DUSC considers a selection of Category 1 and Category 2 submissions to the PBAC</i> ”.

Shortened forms and definitions

Acronyms and abbreviations

Term	Definition
ATAGI	Australian Technical Advisory Group on Immunisation
AUSFTA	Australia – United States Free Trade Agreement
department	Australian Government Department of Health and Aged Care
DUSC	Drug Utilisation Sub-Committee
ESC	Economics Sub-Committee
HTA	Health Technology Assessment
HTAAP	Health Technology Assessment Access Point
MAP	Managed Access Program
MBD	Medical Benefits Division
MSAC	Medical Services Advisory Committee
NIP	National Immunisation Program
NPWP	Nutritional Products Working Party
OHTA	Office of Health Technology Assessment
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PSD	Public Summary Document
RPBS	Repatriation Pharmaceutical Benefits Scheme
RSA	Risk-Sharing Arrangement
SPA	Special Pricing Arrangement
TAAD	Technology Assessment and Access Division
TGA	Therapeutic Goods Administration

Definitions

Applicant

‘Applicant’ refers to the individual or organisation who is responsible for preparing the PBAC submission. The applicant may be a pharmaceutical company responsible for the medicinal product/pharmaceutical item, and/or an organisation or individual supporting the preparation of the PBAC submission.

Business days

Any day that is not a Saturday or Sunday and is not a national public holiday. If a national public holiday falls on a Saturday or Sunday, and the public holiday is observed by all Australian states and territories on a Monday to Friday in lieu of the day, this day is also considered a national public holiday.

Health Products Portal

The Health Products Portal (HPP) is an online system for each applicant to interact with the department to manage PBAC/PBS processes. The HPP can be accessed via the PBS website, in the

‘for Industry’ section. The HPP is being built and released progressively in phases. The [HPP website](#) details which functions are available via the HPP.

Medicine

Medicine refers to a therapeutic good that is represented to achieve, or is likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human. Medicine and drug are interchangeable in this procedure guidance (TGA definition can be viewed on the [TGA website](#)). At times medicine is appropriately read in the context of this guide to include medicinal product, or pharmaceutical item.

Medicinal product

A product containing a medicine. Medicinal products are also known as pharmaceutical products. The medicinal product is listed on the PBS Schedule. This refers to the brand named product (usually the Trade Product Pack in the Australian Medicines Terminology). Ready prepared medicinal products are generally referred to in the *National Health Act 1953* as a brand of pharmaceutical item or pharmaceutical benefit.

Pharmaceutical Item

This is the legal concept of pharmaceutical item, as defined in Section 84AB of the *National Health Act 1953*. It is the drug, form and manner of administration as set out in the main listing instrument for the PBS (currently known as the National Health (Listing of Pharmaceutical Benefits) Instrument, located on the [Federal Register of Legislation](#)). For example, *drugX, tablet 20 mg, oral* would be a pharmaceutical item and *BrandA of drugX, tablet 20 mg, oral* would be a brand of pharmaceutical item.

Responsible person

A responsible person for a brand of a pharmaceutical item is defined in Section 84AF of the *National Health Act 1953* and stated below.

- 1) The Minister may, by legislative instrument, determine that a person is the responsible person for a brand of a pharmaceutical item if:
 - a. the person notified the Minister that the person is or will be the supplier of the brand of the pharmaceutical item to:
 - i. wholesalers; or
 - ii. in the case of a supply where wholesalers are not involved—approved pharmacists directly; and
 - b. the brand of the pharmaceutical item is a listed brand; and
 - c. there is no determination in force under this section that another person is the responsible person for:
 - i. the brand of the pharmaceutical item; or
 - ii. the brand of any other pharmaceutical item.
- 2) The notification referred to in paragraph (1)(a) may be made before or after the commencement of this section.

Submission due day

Submission due day is the date which the department needs to have received applications for a specified evaluation category for the Committee meeting that is to consider that application. The

submission due day for applications in one evaluation category could be different from that for applications in another evaluation category.

1 Purpose

This guide describes the processes undertaken by the Australian Government Department of Health and Aged Care (the department) in considering and listing medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP). It provides information on processes, procedures, timelines and documents required. Information on cost recovery administrative processes is located on the [PBS website](#) and should be referred to in conjunction with this document.

The operation of the Australian Government's subsidy scheme for medicines (referred to as drugs and medicinal products), the PBS, is established by the *National Health Act 1953* (the Act). This Act also establishes the responsibility of the statutory expert advisory committee, the Pharmaceutical Benefits Advisory Committee (PBAC) in its primary role of recommending, to the Minister for Health, which medicines and medicinal preparations should be subsidised by the Australian Government under the PBS and which vaccines under the NIP.

To make a recommendation for subsidy, the PBAC is required to consider both the comparative effectiveness and cost of each medicine, medicinal product or vaccine. The PBAC has endorsed the [Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee](#) (the PBAC Guidelines) to provide information required by the PBAC. The PBAC Guidelines should be considered by any organisation seeking to list a medicine or medicinal product on the PBS or a vaccine on the NIP. Please note that these Guidelines are generally not relevant to listing of a new brand of an existing pharmaceutical item, and not all matters in the PBAC Guidelines will be relevant to all submissions.

1.1 Purpose of this document

This document provides information to:

- support organisations seeking to prepare submissions, including information on the types of, structure and documents required for submissions
- explain the evaluation procedures for medicines and vaccines and management of other PBAC materials
- outline the procedures required to list a medicine or medicinal product on the PBS
- explain how the products on the PBS are reviewed once listed on the PBS

This document is routinely revised to reflect current processes involved in consideration and listing of medicines on the PBS and vaccines on the NIP. Any comments or questions relating to this document should be forwarded to the department (refer to Appendix A).

1.2 Cost recovery

The *National Health Act 1953* provides authority for the cost recovery of Australian Government-funded services from applicants seeking new, or changes to existing, listings of medicines, vaccines and other products or services on the PBS or the NIP. The requirements of cost recovery are prescribed by the [National Health \(Pharmaceuticals and Vaccines – Cost Recovery\) Regulations 2022](#) (Cost Recovery Regulations).

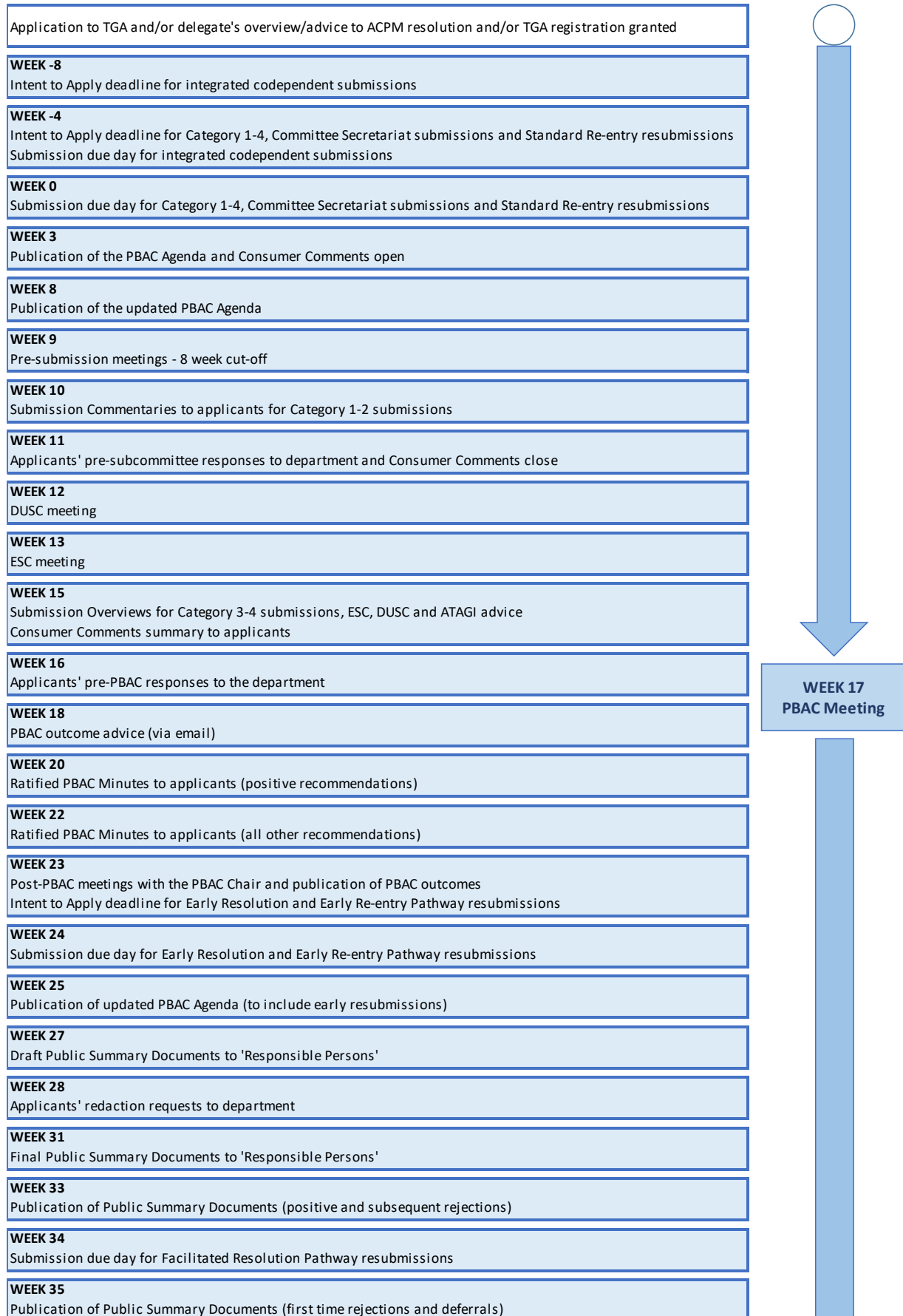
The procedures for cost recovery are undertaken by the department and the applicant. The PBAC, other committees and groups involved in the evaluation or listing processes are not involved in cost recovery administration. Refer to the [PBS/NIP listing Cost Recovery Administrative Guidelines: information for Applicants](#) (Cost Recovery Administrative Guidelines) for information on the cost recovery administration process.

The cost recovery application categories and associated fees are defined in the [Cost Recovery Regulations](#). Further information regarding Cost Recovery is provided on the [PBS website](#).

2 Listing process

The process for submissions and resubmissions to the PBAC is represented in the timeline below.

Figure 2.1 Timeline of PBAC procedures



3 Confidentiality and transparency

The Australian Government, the PBAC and its subcommittees, are conscious of the need to be open and transparent and aim to provide as much information as possible in relation to listing medicines/vaccines on the PBS/NIP. The constraints on providing all information associated with submissions to the PBAC and other listing documents arise generally from considerations of privacy, commercial sensitivity and operation of relevant Commonwealth Acts and Regulations.

A number of Acts made by Parliament are relevant to the management and release of information, which form part of the procedures for listing a medicine/vaccine on the PBS/NIP. The information includes submission documents prepared by applicants, other general submissions to the PBAC, all agenda items considered by the PBAC, and other letters and applications made directly to the department. Relevant Acts include:

- *National Health Act 1953*. This Act establishes the PBS. Section 135A of this Act specifically deals with the protection of information obtained for the purpose of the Act and provides for an offence for inappropriate disclosure
- *Health Insurance Act 1973*
- *Privacy Act 1988*. This Act regulates how personal information is handled, and includes Australian Privacy Principles with which all Australian Government agencies comply
- *Freedom of Information Act 1982*. This Act provides a legally enforceable right of access to government documents
- *Copyright Act 1968*
- *Archive Act 1983*

Specific provisions dealing with the confidentiality of information are provided for in contracts between contractors for services and the government, and deeds of agreement between pharmaceutical companies and the government.

The Australian Government and the Government of the United States of America signed the Australia – United States Free Trade Agreement (AUSFTA) in 2004, which came into effect on 1 January 2005. There are agreed-to principles in relation to transparency and the processes that apply to both countries in managing their respective pharmaceutical programs at the federal level.

These principles are found in Annex 2-C – Pharmaceuticals of the AUSFTA. An explanation of these can be found on the [department's website about the AUSFTA](#).

3.1 Managing and assessing confidential material

3.1.1 Material contained in submissions

Australian Government Department of Health and Aged Care

Electronic and paper-based records are maintained by the department to show what happened, when and how it happened, who was involved, what was decided or recommended, what advice or instruction was given, and the order of decisions or events. The department maintains policies and procedures to ensure the management and storage of records is consistent, accurate and appropriate.

Submissions to the PBAC are made through the [Health Products Portal](#) (HPP). The contents of all submissions and any correspondence received post submission lodgement are stored in the department's IT system as provided by the applicant.

Access to the contents of the submission is limited to officers who need to work on the submission material. Senior officers in the Office of Health Technology Assessment (OHTA) control access.

The contents of submissions are potentially subject to release under Freedom of Information legislation and may be subject to requests of the Parliament.

For information regarding the HPP terms of use, please see [HPP terms and conditions](#).

Contractors evaluating submissions and working on agenda items for the PBAC

The external evaluation entity (see Section 6.2) receives electronic copies of submissions that are allocated for them to evaluate. The conditions of storage, management and disposal of submission material are explicitly stated in the department's contracts.

All people undertaking evaluations or other work for the PBAC require signed deeds of confidentiality. Employees and subcontractors of each external evaluation group agree not to disclose information provided in the submission to a 'third party' – that is, they will maintain confidentiality concerning the content of submissions and other PBAC materials.

Members of PBAC and its subcommittees

All agenda material is provided to committee members in electronic form.

Members of the PBAC and its subcommittees, and any working groups appointed by the PBAC or its subcommittees, are required to sign a deed of confidentiality when appointed. The deed includes text about not disclosing information provided in the agenda papers to a 'third party'.

Members are advised of the requirements to securely handle and dispose of confidential material appropriately, whether electronic or printed.

Other interested parties

From time to time, other parties will need to have information from submissions or PBAC agenda papers released for specific purposes. These include – but are not limited to – giving technical or expert advice, assisting with implementation or providing a consumer perspective. Examples of the people who may have access to this material are other officers within the department, such as the Therapeutic Goods Administration (TGA) and Population Health Division, and non-department employees such as clinicians or other health care professionals, members of the Australian Technical Advisory Group on Immunisation (ATAGI) and its working parties (for vaccine submissions only), employees of the National Prescribing Service, and officers from the Australian Government Services Australia.

Where these other parties are not currently Australian Government employees, they will have access to submission material after they sign a Deed of Confidentiality that includes text about not disclosing any information provided in the agenda papers to a 'third party'. All attendees at meetings are required to dispose of any electronic and paper material appropriately.

3.1.2 Material contained in contracts and deeds

All material in contracts and deeds is managed according to the requirements set out in the contract or deed.

3.2 Managing conflicts of interest

Conflict of interest documents are managed under departmental procedures consistent with the *Privacy Act 1988*, and storage and handling of this personal information is protected. OHTA maintains a record of all conflicts of interest and the actions taken to address these by the relevant evaluation group, committee or other interested parties.

3.2.1 Management of conflict of interest by members of the PBAC and its subcommittees, working groups and advisers

The department takes appropriate steps to identify and manage potential conflicts of interest in relation to submissions to the PBAC. This includes arrangements in relation to departmental staff, committee members, working group participants, advisers and contractors.

Members of committees provide an annual declaration of interests and potential conflicts.

All nongovernment attendees at meetings of the PBAC, subcommittees, working groups or other meetings must confirm whether any additional conflicts have arisen before attending each meeting and at each meeting. A signed declaration is provided by all members for each meeting and stored by the department.

3.2.2 Management of conflict of interest for external evaluation groups

Evaluation entities inform the department of any relevant conflicts of interest in relation to their allocated submissions.

Where there is an unavoidable conflict, the department makes arrangements to manage the identified conflict.

3.3 Managing outcomes processes transparently

Publishing documents as part of the process of listing of medicines on the PBS is consistent with the objectives of the Australian Government's National Medicines Policy. This policy states that consumers and health practitioners should be encouraged to understand the costs, benefits and risks of medicines. Consistent with this policy, both the PBAC and the Drug Utilisation Sub Committee (DUSC) releases outcome statements and reports about the use of medicines that are listed on the PBS.

Currently, three sets of documents associated with the PBAC consideration of medicines and two sets of information about medicine utilisation are publicly released. Further information about these documents is outlined below. The consumer Medicine Status Website also provides information for consumers on the PBS listing process.

3.3.1 PBAC Agenda

A list of submissions that will be considered by the PBAC is published on the [PBS website](#) 14 weeks before the date of the PBAC meeting. An updated agenda will be published 9 weeks before the date of the PBAC meeting to reflect lodgement of Early Re-entry or Early Resolution Pathway resubmissions. Submissions related to requests that only consider the price of a medicine or vaccine are not included on the published agenda.

A list of DUSC reports on the utilisation of listed PBS medicines to be considered by the PBAC at the upcoming meeting is provided at the same time as the list of submissions.

3.3.2 PBAC Outcomes

The outcomes provide the decision and a summary of the reasons for the decision (see Section 7.3).

3.3.3 PBAC Public Summary Documents

[Public Summary Documents](#) (PSDs) are a publicly available version of the PBAC recommendations (the PBAC Minutes) and are usually available 16-18 weeks after the PBAC meeting (see Section 7.4). Publication of PSDs provides information on the evidentiary basis and the rationale for the PBAC recommendations.

3.3.4 Drug Utilisation Sub-Committee Outcome Statements

The [DUSC Outcome Statements](#) provide a high-level summary of the topics discussed at each DUSC meeting. This includes summarised results and DUSC's views on analyses of utilisation of PBS medicines and of therapeutic areas (multiple medicines in a treatment area) considered at that meeting. The Outcome Statement also provides notice of the PBS medicines and therapeutic areas selected for consideration at future DUSC meetings.

3.3.5 Drug Utilisation Sub-Committee Utilisation Analysis Public Release Documents

The DUSC Utilisation Analysis Public Release Documents provide public access to the [DUSC utilisation analysis reports](#). DUSC considers that the reports will assist stakeholders – including consumers, health professionals, researchers and pharmaceutical companies – to better understand how PBS medicines are currently being used, the methods DUSC employs to analyse utilisation of PBS medicines, and the PBS data available for these analyses. The reports may also outline how the current use of PBS medicines in clinical practice compares with the projected use as recommended by the PBAC.

3.3.6 Medicine Status Website

The Medicine Status Website (MSW) centralises the key information available on how to list a medicine on the PBS. It also enable users to track a medicine's progress through the PBS listing process; clearly articulates how consumers can contribute to PBAC decision making; and increases understanding of the activities involved in the PBS listing process.

Further information can be found on the [Medicine Status Website](#) or via the [MSW Factsheet](#).

4 Pre-submission requirements

The department provides a range of documents and services to assist applicants lodging a submission to the PBAC for:

- listing a new medicine on the PBS or new vaccine on the NIP
- listing a new form and strength (pharmaceutical item) of an existing medicine on the PBS or vaccine on the NIP
- requesting a new indication or a change in a component of the listing of a PBS-listed medicine or a NIP-listed vaccine
- consideration of any other matter.

This section also provides information for applicants who want to prepare a submission to list a new brand of medicine on the PBS that does not require consideration by the PBAC.

The timeframes provided in Section 4.3 are relative to the PBAC meeting at which the submission is considered by the PBAC, or during the period before PBS listing dates where the submission is managed by the department. The actual calendar dates each year are published on the [PBS website](#).

4.1 Types of submissions

There are six submission types for listing medicines on the PBS and vaccines on the NIP. These are described in general terms below. Procedures for resubmission pathways are outlined in Section 9, and procedures for reconsideration of a recommendation are outlined in Section 5.7.

The *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* (Refer Part 3: Submission Services) prescribes the requirement for categorising submissions. The descriptions below are a general guide only and in relation to cost recovery matters, this guide does not take precedence over the Cost Recovery Regulations.

Applicants who are uncertain of the appropriate submission category should contact the PBAC Secretariat for advice (refer to contact details in Appendix A). Where a submission is considered by the department to be misclassified, the department will review and reclassify the submission. The process for determining a submission category is outlined in the [Cost Recovery Administrative Guidelines](#).

The department may choose to not accept a submission on the basis it is considered incomplete and does not contain the information required by the PBAC for decision making. The department will notify applicants within 10 business days after lodgement, if their submission is not accepted – refer to the Cost Recovery Administrative Guidelines for more information.

All submissions to the PBAC should adhere, where relevant, to the structure and information requirements set out in the [PBAC Guidelines](#).

4.1.1 Category 1 submissions

These submissions require the PBAC to assess the magnitude of clinical improvement or toxicity reduction, the incremental cost and the comparative costs and outcomes where an economic evaluation is required to support a claim of cost-effectiveness, cost-utility or cost-minimisation.

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.
 - *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.*
 - *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.*
- OR
- A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC.
- OR
- A drug or designated vaccine with a TGA Provisional determination related to the proposed population.

4.1.2 Category 2 submissions

These submissions require the PBAC to assess the magnitude of clinical improvement or toxicity reduction, the incremental cost and the comparative costs and outcomes where an economic evaluation is required to support a claim of cost-effectiveness, cost-utility or cost-minimisation.

Category 2 submissions generally relate to a request for 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.

They 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.

Examples:

A new medicine for a condition that is currently treated OR a new vaccine against a disease for which there is a current vaccine.

OR

A listed medicine for an additional condition OR a listed vaccine for an additional population.

OR

One or more material changes to an existing listing that requires a full evaluation (clinical, economic and financial evaluation).

4.1.3 Category 3 submissions

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.

They 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).

Examples:

A new biosimilar medicine where the reference medicine is already listed for the same population.

OR

A medicinal food. A food that is a therapeutic good within the meaning of paragraphs (a) and (b) of the definition of therapeutic goods in Section 3 of the Therapeutic Goods Act 1989).

OR

A change to an existing listing that does not change the population or cost effectiveness of the treatment; and is not a Category 4 submission.

OR

The request is to change the restriction level of a listed medicine (e.g. Restricted benefit, Authority Required – in writing, Authority Required – telephone/electronic, Streamlined Authority).

OR

The request is to amend or vary an existing deed (e.g. changes to a Risk Share Arrangement).

4.1.4 Category 4 submissions

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 (Exempt item as per subsection 84AH of the *National Health Act 1953*).
- Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing.
- A change to the existing, or the addition of a new form or manner of administration of a listed medicine.
- A change to the maximum quantity and/or number of repeats of a listed medicine.
- A change or addition to the prescriber type(s) of a listed medicine.

Refer to section 4.1.6 and 5.8 for applications that seek the listing a new oral form of an existing pharmaceutical item.

4.1.5 Committee secretariat submissions

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 effect associated with the proposed change to the PBS.

4.1.6 Application for a new brand, or new oral form, of an existing pharmaceutical item

Applications that 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 should be lodged directly to the department. Evidence of equivalence from the TGA must also be provided.

4.1.7 General correspondence to the PBAC

Individuals, organisations and consumers may raise issues for consideration by the PBAC. The format of these submissions is not specified unless there is a requirement to advise the Government of an expected change in government expenditure on the PBS or NIP.

4.2 Guidelines for preparing submissions

The PBAC provides guidance on methodological approaches to be used in the preparation of submissions in the [PBAC Guidelines](#). The PBAC Guidelines contain specified information requirements for fixed-dose combination products, vaccine products and codependent technologies.

Guidance for preparation of Category 3 and Category 4 submissions uses elements of the PBAC Guidelines, which also contain specified information requirements for nutritional products. The structure of these submissions should include appropriate or applicable elements of Sections 1, 2 and 4 of the PBAC Guidelines. In particular, the applicant needs to complete the applicable Section of the [Section 4 - Utilisation and cost model workbook](#) (Excel format) and provide this with the submitted documents.

The structure and requirements for preparing a resubmission are outlined in Section 9.

4.3 Timeframes for the PBS

4.3.1 Key dates for PBAC and subcommittee meetings, submission lodgement

A [PBS calendar](#), which outlines PBAC, DUSC and Economics Sub-Committee (ESC) meeting dates, deadlines for submissions and key post-PBAC dates for advice on PBAC decisions, publication of outcomes and PSDs is available online. Alternative timeframes may apply over the Christmas and New Year period, refer to the [PBS calendar](#) for details.

4.3.2 Timeframes for integrated codependent submissions

Timeframes for integrated codependent submissions are coordinated with the Medical Benefits Division (MBD) on a case-by-case basis.

However, the Intent to Apply form for an integrated codependent submission is required four weeks ahead of the submission due date, and applicants should be aware that the deadlines for integrated

codependent submissions are generally four weeks earlier than the usual PBAC submission due date. Refer to the [PBS calendar](#) for due dates.

4.3.3 Key dates for publication of the PBS Schedule

The department [publishes a list of dates](#) related to provision of key documents for listing and publication deadlines for the PBS Schedule, monthly. This includes lodgement deadlines for new brands of existing pharmaceutical items, and other PBS deadlines (e.g. delisting and price increase requests).

4.4 Pre-submission meetings

The department can provide pre-submission advice on the preparation of submissions that is intended to:

- support applicants in the development of their submissions to the PBAC;
- provide applicants with experienced departmental advice based on understanding of the PBAC guidelines and relevant previous recommendations made by the PBAC; and
- identify other issues that may arise during PBAC's consideration of the submission.

The department may also facilitate joint pre-submission meetings with the TGA, MSAC Secretariat and ATAGI Secretariat officers as appropriate.

Participation in pre-submission meetings is applicant-driven. Applicants will determine whether and when they wish to request a pre-submission meeting within the range of dates available (see the [PBS calendar](#) on the PBS website for available dates).

Applicants should note the following:

- An applicant's participation in a pre-submission meeting does not influence the PBAC's considerations of the submission, and does not guarantee the success of a submission.
- Advice provided by the department in the pre-submission phase is in no way binding on the department, applicant, evaluators or committees.
- Applicants must form their own judgements about how to use departmental advice.
- Members of the PBAC and its subcommittees do not attend pre-submission meetings, to ensure the PBAC decision-making remains independent. Pre-submission meetings cannot advise on or bind what the committee may think or decide.
- Departmental advice may be sought in relation to specific issues including restrictions, comparators, clinical data, economics and financials. However, the pre-submission meeting does not provide an evaluation of any aspects of the proposed submission, including evaluation of data. The department does not confirm or agree with economic approaches, claims or modelling.
- It is recommended that all applicants, including those that have received advice from the department in a pre-submission meeting, should consult the [PBAC Guidelines](#) when preparing their submission.

Pre-submission meetings will generally be available for submissions or resubmissions that meet one or more of the following criteria:

- the requested listing involves a new medicine or a new vaccine that is the first of a class in a therapeutic area, including a new medicine or new vaccine linked to a concurrent TGA Provisional or Priority designation; or

- the requested listing involves a listed medicine for an additional condition OR a listed vaccine for an additional population; or
- the requested listing involves a listed medicine or a listed vaccine that involves one or more material changes to the existing listing that requires a clinical and/or economic and/or financial evaluation;
- the requested listing is a standard re-entry pathway submission with outstanding issues that require a substantial re-assessment of the submission evidence or revision of the economic evaluation model, and further technical advice from the department would provide useful input that cannot be obtained from another source; or
- the applicant is proposing a Managed Access Program (MAP) or complex risk-sharing arrangement (RSA) that is integral to the consideration of the PBAC. Complex RSAs include RSAs that involve collecting additional patient data (e.g. evidence of response) and are also referred to as Performance-based RSAs or Pay for Performance arrangements. MAPs involve prospective collection of evidence (see the [framework for the managed entry scheme](#)).

The pre-submission meeting request allows applicants to nominate representatives from other areas across the department, such as the DUSC Secretariat, ATAGI Secretariat, TGA and/or MSAC Secretariat if broader advice is required for their submission. Applicants cannot request specific individuals within the department. The department will determine which departmental representatives are required to attend the meeting to address the key questions raised by applicants, and departmental representatives will be confirmed with the applicant approximately two business days before the meeting.

A separate pre-submission meeting and fee will be required for each drug and/or indication where multiple PBAC submissions are proposed.

Pre-submission meetings should be fit for purpose. The department reserves the right to decline a pre-submission meeting request, following consultation with the applicant, if a meeting is unlikely to be of value. For example, a meeting may be of limited value in cases where the prospective submission is straightforward and does not satisfy the criteria outlined below. After considering the meeting application, the department may agree or not agree to hold the pre-submission meeting with the applicant.

4.4.1 Requesting a pre-submission meeting

Applicants may request a pre-submission meeting via lodgement of the Pre-submission Meeting Request via the department's Health Products Portal (HPP). Pre-submission meeting requests should be lodged electronically by 5pm (AEDT), at least four weeks before the proposed pre-submission meeting date. The available pre-submission meeting dates are outlined in the [PBS calendar](#) available on the PBS website.

Where one or more pre-submission meetings are intended to occur, the meeting(s) must be held by week 9 of the PBAC cycle prior to the submission due day (i.e. 8 weeks prior to lodgement). Where two (2) meetings are intended, it is recommended that the first meeting is held by week 1 of the PBAC cycle prior to the submission due day (i.e. 16 weeks prior to lodgement).

Where the second meeting relies upon the advice provided in the first meeting, the applicant should ensure there is sufficient time for the applicant to prepare meeting outcomes and for acknowledgement by the department prior to the second meeting briefing paper being lodged.

Table 4.4.1 – Minimum pre-submission meeting timeline

Timeframe	Requirement
Four weeks before the intended meeting date	Lodgement of a pre-submission meeting request
Two weeks before the meeting date	Lodgement of a pre-submission briefing paper
Two days before the meeting date	Confirmation of department attendees
Two weeks after the meeting	Meeting outcomes provided to the department
Four weeks after the meeting	Meeting outcomes confirmed by the department

4.4.2 Arranging a pre-submission meeting

The department will respond to the pre-submission meeting request within 10 business days. The response will:

- acknowledge the request;
- provide meeting dates; and
- provide timelines for lodgement of a briefing paper.

Applicants can contact the department via email at: PBACpresubmissionmeetings@health.gov.au for any further information or questions regarding the meeting.

A standard agenda for the meeting (aligned with the PBAC Guidelines) is included in the Pre-submission Briefing Paper (briefing paper). The indicative times should align with the key questions provided in the briefing paper, which will be used to guide the discussion at the meeting.

Meetings for medicines that are considered integrated codependent submissions are arranged in consultation with the MSAC Secretariat. Applicants should also contact the Health Technology Assessment Access Point (HTAAP) if they have an integrated codependent submission (refer to Appendix A for contact details).

* Note: All templates are available on the [PBS website](#) for applicants to access at any time to assist with their planning.

4.4.3 Pre-submission briefing material

Applicants are required to submit the completed briefing paper at least 10 business days before the scheduled meeting. The purpose of the template is to prompt applicants to identify and articulate key issues, concerns and areas of uncertainty in their submission preparations. This will assist the department to prepare and deliver a more focused discussion and to ensure the meeting is as useful as possible for the applicant. As applicants' interests and concerns will differ, the template serves as a guide only, and applicants are not required to provide responses to all items.

Briefing papers should provide a balance of sufficient detail to gain the required advice, yet should avoid inclusion of detailed data, full study and trial reports or complex model structures. The paper should not include promotional material for the company or medicine/vaccine.

Key questions/points for discussion should include the concerns of the applicant in relation to each topic to help guide preparation for the meeting. In the interests of ensuring the pre-submission discussion is valuable for the applicant, the department may contact the applicant prior to the meeting to seek clarification on information provided in the briefing paper.

If the briefing paper is not provided at least 10 business days before the meeting, the department will decline the meeting date or reschedule the meeting.

4.4.4 Pre-submission meeting attendance

Applicants representatives should be based on the expertise needed to discuss the key questions provided in the briefing paper. Applicants are able to bring employees of their organisations and members of professions such as health professionals or other health service providers. The applicant should advise the department who will be attending the pre-submission meeting and what their role at the meeting will be.

If contracted advisors and any other third-party agents accompanying the applicant to a pre-submission meeting, the applicants are responsible for ensuring these nominated representatives understand and agree to the department's confidentiality requirements. The department welcomes the participation of consumer organisations or clinician input in pre-submission meetings. Conflict of interest declarations will be required as well as confirmation that all aspects of the briefing paper has been fully shared by the applicant with all participants, including consumers.

External contractors attending on behalf of applicants are to participate in a technical role and not in any capacity as a lobbyist. Pre-submission meetings are not for lobbying departmental officers. Lobbying activities are defined as '*communications with a government representative in an effort to influence government decision making, including ... the allocation of funding*'. Additional information about the [Lobbying Code of Conduct](#) is available via the Attorney-General's Department website.

Applicants are able to specify in the meeting request form the areas of the department from which they wish to seek advice. These requests will be assessed against the content of the briefing paper.

Applicants and the department are responsible for ensuring only people contributing to the meeting are in attendance to ensure meeting numbers are kept to a useful number and an effective meeting is able to occur. Applicants and representatives from the department may attend meetings in person, or via teleconference.

4.4.5 Pre-submission meeting agenda

The department treats all agenda and supporting material as in-confidence.

The applicant is requested to provide indicative times for each agenda item included in the briefing paper. The discussion is informed by the briefing paper and key questions.

Pre-submission meetings will be scheduled for one hour.

When closing the meeting, the department may summarise the advice provided. In addition, the department and applicants can provide feedback on their experience of the pre-submission meeting and general satisfaction with the pre-submission meeting process, for evaluation purposes. An evaluation statement from the applicant and the department will be captured in the meeting outcomes record.

4.4.6 Documenting pre-submission meeting outcomes

The meeting outcomes record is the responsibility and at the discretion of the applicant. The meeting outcome record should capture the department's advice provided in response to the key questions discussed during the meeting and must be completed using the template provided by the department.

Applicants are required to return the meeting outcomes record to the department within 10 business days following the meeting. The department will review the meeting outcomes record, and confirm the main discussion points or provide information about discrepancies within 10 business days of receipt. The meeting outcomes record will then be considered final.

If a second pre-submission meeting appears to be likely, the applicant may want to aim to provide the first meeting outcomes record within five business days after the meeting to assist with meeting outcomes record being finalised prior to the second meeting. In these circumstances, the department will aim to reply within five business days of receipt.

Applicants should note that the department's response to the meeting outcomes record remains non-binding, and that the meeting outcomes record is not an opportunity to seek additional advice. Should further advice be required, applicants may request a second pre-submission meeting.

Applicants may choose to attach their pre-submission meeting outcomes record to their submission. However, it should be noted the meeting outcomes record remain non-binding and are guidance to support submission development only. The PBAC will continue to consider submissions according to the relevant information requested in the [PBAC Guidelines](#).

4.5 Integrated codependent submissions

Health technologies are codependent if their use needs to be combined (either sequentially or simultaneously) to achieve or improve the intended clinical effect of either technology. For example, a medicine–test combination, where a new medicine seeking listing on the PBS may have a related pathology test that helps to determine the population group for that medicine.

The PBAC Guidelines (Product Type 4) provide information about when codependent submissions may be required, so that MSAC and PBAC can consider the submission. The department has developed a coordinated approach to managing these submissions.

Applicants who may need to prepare a codependent submission should contact the HTAAP early to facilitate the submission process, including scheduling meetings with the relevant departmental officers from MBD and TAAD if required. Further details are available on the [department's HTA webpage](#). Contact details for the HTAAP are in Appendix A.

Where an applicant is making an integrated codependent submission, the Intent to Apply form is required four weeks prior to the MSAC submission due day. As the MSAC submission date is typically four weeks earlier than the corresponding PBAC submission due day (the MSAC submission due day corresponds with the date of the previous meeting of the Evaluation Sub-Committee of MSAC). As a result, the Intent to Apply form for an integrated codependent submission is required eight weeks before the usual PBAC submission due day and the integrated codependent submission due day is four weeks before the usual PBAC submission due day. Dates are available on the [MSAC calendar](#).

Where a PBAC submission involves a streamlined codependent submission to MSAC the normal PBAC timelines apply.

5 Lodging submissions for listing medicines or vaccines

5.1 Intent to Apply

The HPP is the approved method for lodging an Intent to Apply form which is mandatory for all submissions lodged for PBAC consideration. This form must be lodged by 5pm AEDT, at least 20 business days prior to the relevant submission due day. Different lodgement timeframes apply for resubmissions (refer to Section 9).

Once the form is submitted, applicants cannot change the information in the form. If the applicant has made a minor administration error (for example, an error in the contact details), the applicant must email the PBAC Secretariat about the error so they can update the information.

A submission will not proceed to the PBAC if an Intent to Apply has not been submitted on or by the due date (lodgement dates are available on the [PBS calendar](#)). The only exception is where:

- The department determines that progressing the application is necessary to address an urgent public health need (refer section 30 of the Cost Recovery Regulations).

5.2 Lodging a submission

The HPP is the approved method for lodging submissions for PBAC consideration. Submissions should be lodged by 5pm AEDT on the relevant submission due day (lodgement dates are available on the [PBS calendar](#)). Where an applicant is unable to lodge a submission via the HPP, the applicant is required contact the PBAC Secretariat regarding an alternative method. See Appendix A for contact details.

All submissions are to be written in English and with all currency in Australian dollars.

5.3 Compliance with standard IT capability

All documents should be presented in formats that can be read by Microsoft Word 2010. Excel spreadsheets containing graphs, calculations and models should be presented in Microsoft Excel 2010. The evaluation groups have access to SAS®, TreeAge Pro suite®, Stata® and Excel 2010 @RISK®. The HPP restricts upload of file types to a list of allowed file types. This list is available through the HPP and also on PBS website (refer to [Submission creation and management in the HPP, Quick Reference Guide](#)).

If the applicant would like to provide submission information in another software format, the applicant must contact the department before the submission is lodged (refer to contact details in Appendix A). The limitation on software is related to standard minimum capacity required, but many evaluation groups have additional software capacity. Departmental officers will work with the applicant and external academic evaluation groups contracted to the department, to enable complete evaluation of the submission.

In the event that an evaluation of a submission is stopped or incomplete because the evaluation group cannot access or use the software, departmental officers will notify the PBAC and the

applicant that the evaluation of the relevant section of the submission is incomplete, and analyses or models could not be verified independently.

5.4 Category 1 and Category 2 submissions

Refer to the document table in the [PBAC Guidelines](#) for a checklist of some required documents for Category 1 and Category 2 submissions.

The HPP will guide applicants to provide the required documents, which include:

- **Main body of the submission.** This is a Microsoft Word document presenting the required information specified in the PBAC Guidelines, comprising an executive summary and up to five sections. A checklist for the executive summary can be downloaded from the [checklists and templates section of the PBAC Guidelines webpage](#).
- **Submission cover letter** on company letterhead signed by an authorised company representative.
- **TGA documents.** The following documents are to be provided, where and when available up to one week before the PBAC meeting:
 - TGA clinical evaluator’s report
 - TGA delegate’s overview
 - Minutes of the Advisory Committee on Medicines
 - TGA risk management plan
 - confirmation of registration in the Australian Register of Therapeutic Goods
 - the most recent Product Information
 - Australian Public Assessment Report for prescription medicines (AusPAR).

Refer to Section 6.3 for additional information about providing documents where submissions are being evaluated under TGA parallel processing.

- **Key documents.** The following completed documents are required by the department:
 - complete and approved Australian Digital Health Agency AMT Mapping form (in Microsoft Word).
- **References.** Separate electronic copies of all papers referenced in the submission, including all published copies of the relevant trials. The references must include the main published paper (where available), together with adequate details of the trial methods, analyses and all trial results presented in the submission for use in the economic evaluation; or the main published paper alone if the applicant has no access to any more detailed report. These materials must be legible and in English (or be accompanied by a reputable translation).
- **Appendixes.** Copies of supporting material, such as supporting studies for Sections 3 and 4, market research reports, and expert advice surveys.
- **Attachments.** Any required attachments provided as separate documents or files, such as
 - any clinical study reports, trial protocols and amendments. The attachments for clinical trial reports must provide the full clinical trial report and a synopsis or summary of the trial report. The list of appendixes for the clinical study report should be provided, but the appendixes are not required in the submission.
- **Models and financial estimates workbook.**
 - Fully executable Section 3 models, including any cost-minimisation spreadsheet
 - Fully executable Section 4 financial estimates Microsoft Excel workbook (also known as the Utilisation and Cost Model).

Where an analysis requires a computer program to generate information for Section 3 or 4 of the submission, provide sufficient information (input data, description of methods used to conduct the analysis, outputs and electronic copy), so that the analysis results can be independently verified, and the validity of the methods of analysis can be assessed.

If any of the analyses in the submission used specific computer software, provide a copy of all relevant electronic files of the statistical analyses and economic evaluation presented in Section 3 or 4 of the submission, and a technical document or an attachment to the submission to give details of calculations. Provide clear cross-references, as appropriate, between the technical document or attachment, and the relevant item in the main body of the submission and for the extraction of data from each source (to the level of the page, table or figure number of the source document).

Where possible, supply the dataset in the form that was used for the analysis. This might be:

- Microsoft Excel files
- flat files (i.e. relatively unformatted ASCII files; typically with file extension txt or dat) with little or no formatting beyond comma or tab separation of values (which are accessible by most widely used statistical programs)
- SAS datasets.

If any intermediate file processing, reformatting and/or file concatenation is required for the preparation of the input data for the actual statistical analysis, provide the computer code(s) required to do this.

Provide the full details of the variable names, order and format (e.g. whether a data value is a date or time in a certain format, a string or a numerical value with a particular precision) if these are not clearly apparent from the data input section of the analysis code.

5.5 Category 3 and Category 4 submissions

The HPP will guide applicants to provide the required documents, which include:

- **Main body of the submission.** Category 3 and Category 4 submissions require relevant information requested in Sections 1, 2 and 4 of the PBAC Guidelines. These submissions also need to estimate the financial cost to the Australian Government of the PBAC recommending the request for the PBS and the Repatriation Pharmaceutical Benefits Scheme (RPBS) or for the NIP.
- **References.** Separate electronic documents for any and all references used in the submission (optional).
- **Appendixes.** Copies of any supporting material for Section 4 (optional).
- **Financial estimates workbook.** Fully executable Section 4 financial estimates Microsoft Excel workbook (also known as the Utilisation and Cost Model).
- **Model.** Fully executable Section 3 model, where applicable.

The following documents are not generally required for these submissions, but may be necessary in certain circumstances:

- A positive TGA Delegate's Overview if the medicine is not registered on the Australian Register of Therapeutic Goods at the time of submission lodgement

- completed and approved Australian Digital Health Agency AMT Mapping form (in Microsoft Word)
- a TGA bioequivalence or equivalence statement.

If the submission concerns a first new brand of a new pharmaceutical item for a drug on F2 (already on F2 or the listing would result in the drug moving to F2) the originator brand determination issues mentioned at Section 5.8 will be considered. Any comments relevant to potential determination as an originator brand should be included in the submission or a letter of application (see Section 8.5.1).

5.6 Committee secretariat submissions

Committee secretariat submissions are prepared in the same way as Category 3 and Category 4 submissions.

The main body of the submission must demonstrate the medicine, medicinal product or vaccine presents no greater risk to a patient than the risk of using an already listed drug or designated vaccine.

5.7 Reconsideration of a Recommendation

Applicants who choose to request reconsideration of a Recommendation are required to:

- Advise the department via the Notice of Intent to Pricing Form (refer to Section 8.2)
- Follow the processes in Section 5 for Lodging a Submission, including lodging an Intent to Apply form (refer to Section 5.1) and following the submission requirements outlined in Section 5.4 or 5.5 based on the type of submission being lodged.

5.8 New brand or new oral form of existing pharmaceutical item submissions (not requiring PBAC consideration)

The PBAC does not generally consider submissions for new brands or new oral forms of existing pharmaceutical items that are not biosimilars (see Section 4.1.3 and 4.1.4).

The departmental delegate considers a submission to list a new brand or new oral form of an existing pharmaceutical item. When listing a new brand of a medicine on the F2 formulary, the delegate may decide to determine the new brand an 'originator brand'. Further information about originator brand determination is available in the [Fact Sheet about 2015 Price Disclosure changes](#) in the [National Health Amendment \(Pharmaceutical Benefits\) Bill 2015 Explanatory Memorandum](#).

Submissions for a new brand or new oral form of an existing pharmaceutical item must include a statement from the TGA to show that it is appropriate for an equivalence indicator to be shown on the PBS Schedule for the new brand or new oral form and currently listed brands or forms that can be prescribed. In some instances, the new brand or new oral form may not have TGA approval for all indications of the currently listed brands. In this event, the applicant should only apply for PBS listing for the TGA approved indications and the new brand or new oral form will only be listed for the approved indications. If this product is not entered in the Australian Register of Therapeutic Goods when the Department is processing this application it may not proceed to listing on the PBS.

The HPP is the approved method for lodging new brand or new oral form of an existing pharmaceutical item submissions. The HPP will guide applicants on the documentation required for this submission type. Where an applicant is unable to lodge a submission via the HPP, the required documents for making a new brand or new oral form of existing pharmaceutical item submission are specified in Part C of the [Application Form for Submission Services](#). The contact details for lodging submissions for new brands of existing pharmaceutical items that do not require PBAC advice are provided at Appendix A2.8.

The contact details for all Pricing related questions and for sending the PB11a form are provided at Appendix A2.6.

Please note that the Department of Veterans' Affairs (DVA) manages the Repatriation Pharmaceutical Benefits Scheme (RPBS). Applications to list new brands on the RPBS Schedule must be directed to DVA at Repatriation.Pharmaceutical.Reference.Committee@dva.gov.au. Applications for RPBS listings cannot be processed by the HPP; inclusion of RPBS item codes in an HPP submission may cause that submission to be rejected.

5.9 Providing documents after lodging a submission

Additional regulatory documents may be updated while the submission is being considered by the PBAC. Applicants should provide the PBAC with electronic versions of any TGA documentation such as updated Product Information, confirmation of registration on the Australian Register of Therapeutic Goods, an AusPAR or a TGA Risk Management Plan.

For submissions evaluated under the TGA parallel process, any relevant TGA documents not available when the submission is lodged (including the clinical evaluator's report, TGA delegate's overview and the recommendation of the Advisory Committee on Medicines) should be provided to the department as soon as possible.

New clinical evidence or cost-effectiveness analyses are generally not accepted once evaluation of submissions is under way. However, if the applicant becomes aware of new publications or further data analyses that have relevance to consideration of the submission by the PBAC, the applicant should contact the PBAC Secretariat to discuss the potential effect of this information (refer to Appendix A for contact details).

6 Procedures for consideration of submissions

The PBAC is a statutory body whose membership and roles are prescribed in the *National Health Act 1953*. The committee undertakes a number of functions including:

- recommend medicines to the Minister for Health for funding under the PBS, and whether the medicine is only available under special supply arrangements (s100 of the National Health Act)
- recommend vaccines to the Minister for Health for funding under the NIP
- recommend the circumstances in which a medicine be funded (i.e. restriction wording, access with authority)
- advise the Minister for Health about cost-effectiveness (value for money) which includes cost (overall budget implications)
- advise the Minister for Health on particular matters related to exempt items, combination items and therapeutic groups
- advise the Minister for Health on provisions for early supply
- advise the Minister for Health about any other matters relating to the PBS/NIP. This includes regular advice on
 - arrangements for risk sharing and managed access
 - price disclosure ‘no reduction’ items
 - recommending the maximum quantities (maximum amounts for chemotherapy infusibles) and repeats
 - schedule equivalence (for substitutability at the point of dispensing)
 - bioequivalence and biosimilarity
 - review of PBS items

6.1 PBAC subcommittees

Under the Act, the PBAC may also establish subcommittees to help it perform its functions. There are currently two subcommittees – ESC and DUSC.

6.1.1 Composition of PBAC and its subcommittees

The members provided for in the Act are appointed by the Minister for Health, and include medical practitioners (specialists, general practitioners and clinical pharmacologists), pharmacists, consumers, health economists and industry representatives. The membership is published in the Government Gazette and details are available on the [PBS website](#).

The Minister for Health appoints the PBAC Chair and the Deputy Chair.

The membership of DUSC includes clinicians, pharmacists, pharmacoepidemiologists, industry representatives and consumers who have a broad range of relevant expertise in the evaluation of medicine use. The membership of DUSC is published on the [PBS website](#).

The membership of ESC includes clinicians, clinical epidemiologists, health economists, biostatisticians and clinical pharmacologists who have a broad range of relevant expertise in clinical epidemiology and health economics. The membership of ESC is published on the [PBS website](#).

6.1.2 Role of the Economics Sub-Committee

ESC reviews and interprets economic analyses submitted by the applicant and the evaluations performed by evaluation entities on submissions to list medicines on the PBS. ESC advises the PBAC on the quality, validity and relevance of these submissions. ESC is also responsible for advising the PBAC on methodological developments on the collection, analysis and interpretation of clinical and economic data.

The subcommittee also provides advice on the content of the PBAC Guidelines.

Selection of submissions and reports for consideration

ESC considers all Category 1 and Category 2 submissions to the PBAC. ESC reviews the information provided in the submission and considers the commentary prepared by the evaluation group (refer to Section 6.2.2) and the TGA documents provided. ESC identifies important uncertainties and key issues for the PBAC about listing the medicine on the PBS or the vaccine on the NIP.

ESC also reviews reports on currently listed medicines where there are potential issues of comparative clinical effectiveness and cost-effectiveness.

How ESC provides advice to the PBAC

ESC advises about selected submissions to the PBAC as a document called the ESC Advice. ESC advice is also provided to the applicant.

6.1.3 Role of the Drug Utilisation Sub-Committee

DUSC monitors the patterns and trends of medicine use, and makes such data publicly available.

DUSC considers a selection of Category 1 and Category 2 submissions to the PBAC. DUSC advises the PBAC and the applicant on important matters relating to use and cost, and reviews utilisation of currently listed PBS medicines.

Selection of submissions and reports for consideration

DUSC generally does not consider submissions where the estimated use and cost of the medicine, or a medicine of the same class, for the indication has already been reviewed, or where previous DUSC advice has been incorporated into the submission. DUSC does not consider submissions only relating to pricing matters, or where the utilisation and cost issues are unlikely to be substantially altered by the addition of the new medicine to the PBS. Examples of the latter include where there is a small clearly defined patient group, or the market is stable or where the medicine is for a non-PBS program.

How DUSC provides advice to the PBAC

DUSC advises and reports about selected submissions to PBAC as a document called the DUSC Advice. The DUSC Advice is also provided to the applicant.

6.2 Evaluation of submissions

All Category 1 and Category 2 submissions have information requirements that address clinical, economic, financial and medicine use matters. These issues may be complex, and need to be carefully evaluated in accordance with the PBAC Guidelines, and with the principles of HTA.

The department engages suitably qualified and experienced entities to assess submissions of pharmaceutical products and vaccines, and undertake project work related to PBS listings.

Each evaluation entity is required to demonstrate efficient and effective processes to manage the documentation appropriately, consistent with the department's confidentiality and conflict of interest requirements.

6.2.1 Role and composition of external evaluation entities

To provide the best evaluation of submissions for the PBAC and its subcommittees, evaluation entities are required to:

- undertake evaluations in a given timeframe
- remain up to date with the latest methodological developments in HTA
- have adequate quality assurance processes
- be prepared to work with OHTA

The department undertakes an open tender process approximately every four years, to engage suitable entities to evaluate submissions.

6.2.2 Conduct of the external evaluation process

Evaluation entities are allocated Category 1 and Category 2 submissions to evaluate. The entities have up to 10 weeks to review the clinical, economic, financial and medicine use information provided in each submission.

An evaluation document, known as a 'commentary', is prepared for each allocated submission. The commentary is included in the agenda papers of DUSC, ESC and the PBAC, and is also provided to the applicant. The applicant can provide a response, the 'Pre-subcommittee response', for the PBAC and ESC, and where the submission has been selected, for DUSC to consider.

The evaluation entity can support ESC during consideration of submissions. ESC can request additional analyses of the clinical information, the economic model or financial estimates. These are provided to the PBAC with the ESC Advice. The additional analyses are also provided to the applicant with the ESC Advice.

6.3 Management of parallel process submissions

The [TGA–PBAC parallel process](#) allows applicants to submit Category 1 and Category 2 submissions relating to medicines and vaccines to be evaluated and considered by the PBAC at any time from the lodgement of a TGA registration dossier.

Applicants are required to have lodged a registration dossier with the TGA prior to making a submission to the PBAC. Vaccine submissions must also include advice from the Australian Technical Advisory Group on Immunisation (ATAGI), and the submission must have addressed matters raised

in the ATAGI advice prior to lodgement of the submission to the PBAC. The applicant is responsible for providing the PBAC with all TGA documents that it receives after lodging a submission. It is preferable that the documents are received as early as possible in the evaluation process (refer to Section 5.9). The PBAC will defer making a decision where there is specific or missing information that cannot be obtained from the applicant and is required for PBAC decision-making (e.g. TGA delegate's overview or MSAC advice in relation to a codependent technology).

A medicine will not be listed on the PBS before it is registered on the Australian Register of Therapeutic Goods.

The PBAC outcomes for items submitted under parallel process that are recommended or deferred, will not be published until a positive delegate's overview has been received, and the Public Summary Document will not be published until the medicine is registered for that indication by the TGA. The PBAC outcome and Public Summary Document for items submitted under parallel process and receiving a rejection will be published in accordance with the standard timeframes.

Parallel processing is not available to Category 3, Category 4 and Committee Secretariat submissions to the PBAC or submissions requesting the listing of a biosimilar medicine. A positive TGA Delegate's Overview should be available at the time of lodgement for submissions lodged in these categories.

Further information about the arrangements for parallel process submissions is available on the [PBS website](#).

6.4 Input of the applicant into the PBAC consideration

The government aims to ensure that the processes for considering public subsidy of medicines and vaccines are transparent to all stakeholders.

Applicants with submissions being considered by the PBAC are able to respond to evaluations of the submissions and other technical documents provided to the PBAC.

Responses are opportunities to clarify, explain and reanalyse information in the submission. Additional clinical trial information or substantially amended models are not acceptable for inclusion in responses, because there is usually no opportunity to evaluate new data or models (both economic and financial). If new data are provided, the PBAC can decide whether it will consider this at the meeting or defer its consideration pending evaluation of the information.

For Category 1, and Category 2 submissions applicants have two opportunities to provide written input, the pre-subcommittee response and the pre-PBAC response, and one opportunity to present comments to the PBAC in the form of a hearing.

For Category 3 and Category 4 submissions applicants have one opportunity to provide written input for the PBAC. This input is called the pre-PBAC response.

6.4.1 Pre-subcommittee response

Applicants receive the commentary on Category 1 and Category 2 submissions on Wednesday of week 10 of the PBAC cycle, which is prior to the meetings of ESC and DUSC. Applicants who choose to provide a response to the department for inclusion in ESC's and DUSC's agenda papers are required to do so by midday Wednesday of week 11 of the PBAC cycle. Refer to the [calendar of dates published on the PBS website](#) for dates applicable to each meeting.

Responses to evaluations of these submissions are limited to four pages of text, and two pages of graphs and tables. Where the evaluation is for an integrated codependent submission, the applicant is allowed ten pages for text, and four pages of graphs and tables. This response is considered by both the PBAC and MSAC.

6.4.2 Pre-PBAC response

In addition to the commentary, each applicant with a Category 1 and Category 2 submissions under consideration by PBAC will receive an ESC Advice and a DUSC Advice (if applicable), plus any additional technical documents that will be provided to the PBAC.

For Category 3 and Category 4 submissions, applicants receive a document called an overview. This is usually prepared by the department for the PBAC. DUSC can also be asked to consider issues in relation to these submissions and, if this is the case, the DUSC Advice is also given to applicants.

Applicants with special products – for example, vaccines – may receive additional information. Further information on advice prepared for the PBAC about submissions for vaccines, nutritional products, contributions through consumer comments and additional information provided to PBAC is provided in the following sections (e.g. vaccines is in Section 6.5).

Applicants who choose to prepare and provide a pre-PBAC response to the department for inclusion in the PBAC agenda papers are required to do so by midday on the [Wednesday of week 16 of the PBAC cycle](#).

Responses for all agenda items considered by the PBAC should be no longer than three pages. For integrated codependent submissions, applicants may provide six pages.

6.4.3 PBAC hearings

An applicant submitting a Category 1 or Category 2 submission, can make an oral presentation to the PBAC during the PBAC meeting. The content of these presentations is limited to matters raised in the submission, during the evaluation, or as part of the advice prepared by the subcommittees. No new evidence is to be presented at this stage.

6.4.4 Procedures to request a hearing

An applicant requesting a hearing should contact the department (refer to contact details in Appendix A) at least eight business days before the PBAC meeting. Applicants should provide the names of personnel attending, and whether an electronic presentation will be used for the hearing. Where the attendees are not employees of the applicant who prepared the submission, the names and affiliations of each person should be supplied at least five business days before the PBAC meeting. Each invited non-employee of the applicant will need to provide a conflict of interest statement.

6.4.5 Preparation for hearing

Each hearing lasts up to 10 minutes. An accompanying electronic presentation is acceptable. Microsoft PowerPoint 2010 is supported by the department. The presentation needs to be provided to the PBAC Secretariat on the Friday before the PBAC meeting. The applicant should ensure that the non-employees attending the hearing are conversant with the contents of the submission and the issues arising during the evaluation process.

The PBAC can ask those attending questions about the content of the submission, clinical practice and quality use of medicine or vaccine issues associated with listing the medicine or vaccine.

6.5 Role of the Australian Technical Advisory Group on Immunisation for requests to list vaccines

ATAGI advises the Minister for Health on the National Immunisation Program (NIP) and other related issues. It is a non-statutory committee comprising experts in immunisation, public health, infectious diseases and consumer issues, as well as medical practitioners and nurses.

ATAGI meets six times a year in February, April, June, August, October and December. Generally, three of these meetings are held face to face, the remainder via videoconference.

ATAGI provides advice to the PBAC on matters relating to the ongoing strength of evidence pertaining to existing, new and emerging vaccines – specifically about their effectiveness and use in Australian populations. ATAGI's terms of reference and strategic intent are available through the [Immunisation website](#) on the department's website.

One of the major roles of ATAGI is to provide the PBAC and ESC with technical advice in relation to the consideration of listing a vaccine on the NIP and the PBS if required.

The ATAGI Secretariat is located in the department. The Secretariats of ATAGI and PBAC liaise regularly to ensure both committees work effectively together to consider submissions for vaccines.

6.5.1 Preparation of technical advice for submissions to consider vaccines

ATAGI has a number of horizon-scanning methods, and may be aware of the existence of a new vaccine before being approached for advice to be prepared on a submission. The horizon scanning includes:

- presentations by vaccine manufacturers at the annual ATAGI Industry Day
- reviews of literature and decisions by regulatory authorities in other countries
- TGA advice to ATAGI regarding new applications for registration.

A preliminary meeting is available to applicants prior to deciding to request ATAGI advice, to ensure the proposed vaccine is suitable for public funding.

6.5.2 Pre-submission advice

Industry applicants of vaccines seeking listing on the NIP schedule are required to obtain advice from ATAGI prior to providing a submission to the PBAC. Applicants are required to make a formal request for ATAGI pre-submission advice through the ATAGI Secretariat following the *Guidelines for preparing a request for advice from ATAGI* to support PBAC considerations of vaccines.

The ATAGI Secretariat, in consultation with the ATAGI Chair, will determine if the request is a simple or complex submission based on the definitions outlined in the [Procedures for ATAGI advice to the PBAC](#).

All requests are required to be lodged according to the published submission calendar for the ATAGI meeting in which the advice is to be endorsed (refer to the [ATAGI website](#)).

Applicants are expected to include the ATAGI pre-submission advice as part of the submission to the PBAC.

Further details on the guidelines, submission calendar, procedures and templates for preparing a request for ATAGI advice is on the [ATAGI website](#).

6.5.3 ATAGI consideration of the content of the submission

Once the request has been received by ATAGI Secretariat, it will be passed onto an independent Vaccine Evaluation Group who will assess and draft advice for ATAGI's consideration.

ATAGI considers this advice at its next face-to-face meeting.

Applicants with questions for ATAGI regarding the ATAGI pre-submission advice or the processes for listing vaccines on the NIP should contact the ATAGI Secretariat (refer to contact details in Appendix A).

6.5.4 Response to questions raised during the evaluation (post-submission advice)

During the evaluation of the submission, the evaluation entity prepares a list of questions relating to the listing of the vaccine for ATAGI's consideration.

ATAGI's response to these questions forms part of the post-submission advice. ATAGI endorses its post-submission advice at one of its face-to-face meetings. The document is then provided to ESC, the PBAC and the applicant.

For some cases, the PBAC may also seek additional information from ATAGI before a vaccine can be listed on the NIP.

6.5.5 ATAGI's role at ESC meetings

When ESC considers a vaccine submission, representatives from ATAGI and the ATAGI Secretariat attend the discussion. ATAGI members are available to answer any additional questions raised during the ESC discussion. A copy of the ESC Advice on a vaccine is provided to the ATAGI Chair. ESC Advice is also provided to the applicant and PBAC (refer to Section 6.1.2).

6.5.6 ATAGI's role at PBAC meetings

The Chair of ATAGI and the ATAGI Secretariat attend the discussion of vaccine items at the PBAC meeting and the Chair is available to answer any questions raised during the PBAC discussion.

6.5.7 After the PBAC recommendation

Where the PBAC makes a positive recommendation to list a new vaccine (or vary an existing vaccine listing) on the NIP, Population Health Division will start the necessary steps to amend the National Health (Immunisation Program-Designated Vaccines) Determination (refer to Section 8.7). Where a vaccine is recommended for listing on the PBS this will follow the usual process for PBS medicines. For management of cases where the PBAC recommends to defer or 'not recommend' a vaccine submission, refer to Section 7.1.

6.6 Role of the Nutritional Products Working Party

A limited number of nutritional products (medicinal foods) are listed on the PBS – special infant oral formula and food substitutes to treat inborn errors of metabolism. The PBAC constituted the Nutritional Products Working Party (NPWP) to provide advice to the PBAC on clinical and financial matters in submissions to list these products on the PBS as well as any matters relating to utilisation of PBS-listed nutritional products referred to them by the PBAC.

The NPWP provides advice to the PBAC on clinical and financial matters in the submission. The NPWP may also consider issues from submissions for nutritional products deferred or not recommended by the PBAC.

Applicants seeking to list a new medicinal food on the PBS must provide a Category 3 submission to the PBAC, consistent with the requirements outlined in the [PBAC Guidelines](#) for Product Type 2.

Submissions for nutritional products are forwarded to the NPWP for consideration at their meeting. The members meet in [week 10 of the PBAC cycle](#).

6.6.1 How the NPWP provides advice to the PBAC

Applicants receive a copy of the NPWP Advice to the PBAC. The applicant has the option to address issues raised by the NPWP in a pre-PBAC response to the PBAC. This should be no longer than three pages of text. The response must address any issues raised by the NPWP or in the submission. No new information can be provided to the PBAC.

6.7 Consumer input

Patients are central to the quality use of medicines and vaccines. The PBAC is committed to understanding consumer perspectives, and integrating them into its consideration of medicines and vaccines.

Currently, consumers are able to provide their views about medicines or vaccines on each PBAC agenda via a web interface. This is under review, and improvements to gather consumer input in ways that will promote meaningful and useful contributions to the PBAC's consideration of medicines are under development.

Consumer information helps the committee understand what consumers consider to be the main benefits and harms of the proposed medicine or vaccine. These may be different from those measured in the clinical trial evidence presented in the submission.

6.7.1 How to make consumer submissions to PBAC

The PBAC agenda is published on the PBS website 14 weeks before the PBAC meeting. The PBAC agenda is updated 9 weeks before the PBAC meeting to reflect lodgement of Early Re-entry or Early Resolution Pathway resubmissions.

Consumers are invited to make comments (electronic format) that are submitted directly to the department. There are eight weeks to make comments for most submissions, and three weeks for Early Re-entry or Early Resolution Pathway resubmissions. Any organisation or individual may make comments. The form is available on the [PBS website](#).

Where consumers are unable to access the website, they should write a letter using the same format and post it to the department (refer to contact details in Appendix A).

6.7.2 How consumer information is managed

Consumer comments are provided to the PBAC's consumer representative, who reviews and collates the comments for the PBAC agenda.

All comments received will be considered by the PBAC. Issues from individuals, with names removed, will be summarised for the applicant and the PBAC. The complete summary of comments from groups or organisations will be provided to the PBAC and the applicant.

6.7.3 How the PBAC uses consumer information

The PBAC considers the consumer comments when considering the relevant agenda item. These are considered at the same time as other technical papers in consideration of the request for listing or amending the listing. The consumer representative highlights consumer issues for each agenda item for the committee's consideration during the discussion of the item at the PBAC.

Consumer comments are summarised in the PBAC Minutes and noted in the Public Summary Document for the submission.

6.8 Additional clinical input

Additional information may be sought before or after the PBAC considers a submission.

Before the PBAC consideration, the department, the evaluators or members of the subcommittees may identify issues that would benefit from clarification or further information to improve the PBAC's consideration of the submission.

The PBAC may also request that the department seek further information after its consideration of the submission. This could be information for inclusion in a resubmission or to assist the department in ensuring that the recommendation to list the medicine or vaccine clearly identifies the eligible, cost-effective population, and is expressed in a way that is understandable and clinically relevant for prescribers and other health professionals.

In general, the matters for which additional input is sought include:

- possible barriers to implementation of a restriction
- quality use of medicines/vaccines
- public health issues that may be associated with listing a medicine/vaccine, such as increasing antibiotic resistance for medicines
- system issues that could affect equity and access for PBS-listed medicines
- clarification with clinical experts about appropriate descriptions for the restriction wording

The PBAC Secretariat will advise the applicant if additional information is sought, and from whom. Where the responding organisations or individuals agree to release their information to the applicant, a copy of the requested information will be provided.

6.8.1 When and from whom additional input is sought

Information is generally sought from relevant representative organisations that the department or the PBAC considers to be best placed to provide timely and accurate advice.

The PBAC and the department are aware that organisations and representative bodies need sufficient time to form an adequate and informative response, and the department seeks to work with these bodies to achieve the best response in the most efficient way. Organisations and representative bodies can request that their responses be treated as confidential, that is, the document will only be circulated as part of the PBAC agenda papers.

Information provided to the PBAC can form part of the PBAC Minutes, the PBAC Outcomes and the Public Summary Document.

6.9 PBAC and subcommittee members attending other meetings

Organisations, academic groups and pharmaceutical companies may request a representative from the PBAC, or its subcommittees or working groups, to attend meetings or make presentations about:

- previously published outcomes in relation to submissions
- issues arising from the PBAC Guidelines
- PBAC processes

All requests will be considered by the PBAC Chair, who may take requests to the full committee if needed.

The PBAC can nominate specific members to represent the PBAC on other committees, or hold joint membership with other committees.

Where PBAC organises meetings with other entities, PBAC members can attend to represent the PBAC with the Chair's out-of-session or the committee's approval. Such meetings include meetings with the representative pharmaceutical industry bodies, such as Medicines Australia, and meetings with stakeholders.

6.10 Stakeholder meetings

6.10.1 Purpose of stakeholder meetings

The PBAC can convene stakeholder meetings with stakeholders:

- Where there is a submission for a medicine that has not been recommended or deferred. In this scenario, meetings are allocated by the PBAC for medicines that treat serious, disabling or life-threatening conditions, where there are no other realistic treatment options for that condition, but where insufficient cost-effectiveness prevents PBAC from recommending listing.
- Where the committee is aware that applicants are preparing to submit submissions for new and innovative therapies to treat diseases with a high patient and public health burden.
- To help inform issues such as the correct place of medicines in treatment regimens, the appropriateness of target populations or choice of comparator.

A meeting of all relevant stakeholders aims to provide the PBAC and stakeholders with a greater understanding of the issues and suggest ways to resolve some of the outstanding matters.

These meetings provide information, and are not a de facto appeals mechanism.

Stakeholder meetings do not replace pre-submission or post-PBAC meetings between the department and the applicant.

Meetings with stakeholders will not be convened where there is legal action pending, such as a submission to the Federal Court for an extension of time in which to file for a review of a decision.

The applicant may request the PBAC to consider convening a stakeholder meeting. The request should outline how the stakeholder meeting will benefit consideration of the medicine for listing by the PBAC.

6.10.2 Conduct of the meetings

The department may invite the following to stakeholder meetings:

- representatives of relevant organisations, both clinical and consumer-based. Attendees of organisations may not be a legal advisor (internal or external)
- applicants making submissions to list and those with current PBS-listed medicines treating the condition
- individual clinical experts with expertise in prescribing, managing and administering the treatment
- consumers with the disease or condition

Meetings are conducted in accordance with the Secretary's Instructions for the department. Attendees will be required to complete confidentiality statements and conflict of interest declarations.

The department will set a date for the meeting and locate a venue that is as convenient and timely as possible.

All stakeholders will be invited to contribute items to the agenda. They will receive a list of attendees and organisations that were invited to provide representatives. A complete set of PBAC Minutes and, where relevant, subcommittee advice will be included in the agenda: commercial in confidence information will be redacted where required. The PBAC may also request presentations from the department on use and cost-effectiveness issues. Stakeholders may be invited, or can offer, to present a full range of perspectives for consideration by the attendees at the meeting.

6.10.3 Outcomes of the meeting

The PBAC Secretariat will provide all attendees with a copy of the draft outcomes of the meeting and an opportunity to make comments or changes. The attendees will be asked to ratify the outcomes. Different points of view and different perspectives will be outlined in the outcomes. The attendees are expected to ratify the outcomes within 15 business days of the meeting. Attendees will receive five business days to review, comment on and ratify the outcomes.

The department will publish the outcomes on the PBS website.

6.10.4 Publication of outcomes

Publications resulting from the meeting may include:

- outcomes of the issues discussed at the meeting, conclusions and any actions arising
- a statement of outcomes of the meeting for public release
- formation of a suggested restriction
- formulation of research questions to address information needs identified by the PBAC consideration, such as those that may be used to develop and implement performance-based RSAs or MAPs

6.11 Codependent submission processes

6.11.1 Integrated codependent submission processes

The same evaluation group evaluates the medicinal and medical service components of an integrated codependent submission (Category 1 submission) where possible. A single evaluation document is prepared for MSAC and the PBAC. This evaluation document is considered by the economic subcommittees of PBAC and MSAC at a joint meeting. Dates are available on the [MSAC calendar](#).

A joint ESC Advice document is prepared for the PBAC and MSAC.

6.11.2 Streamlined codependent submission processes

Where a Category 2 submission is lodged for PBAC consideration, lodge the accompanying streamlined submission to MSAC at the same time. Standard PBAC processes apply to the Category 2 submission to the PBAC. An overview of the streamlined submission to MSAC is prepared by the department and will be provided to the applicant according to the standard pre-MSAC process.

7 Post-PBAC procedures for applicants

7.1 Notification of outcomes of PBAC

Table 7.1 shows the timeframe for notification of PBAC outcomes.

Table 7.1 Timeframe for notification of PBAC outcomes

Timeframe	PBAC outcome provided
One week after PBAC meeting	Emailed advice of type of PBAC outcome including any PBAC nominated pathways (recommended and not recommended submissions)
Three weeks after PBAC meeting	Ratified PBAC Minutes for positive recommendations by email (Section 7.1.1)
Five weeks after PBAC meeting	Ratified PBAC Minutes for deferred and not recommended submissions by email (Sections 7.1.2 and 7.1.3)

7.1.1 Receipt of positive recommendation

For a positive recommendation, written advice (the PBAC Minutes) is provided to the applicant on Friday of week 20 of the PBAC cycle (three weeks after PBAC meeting). These Minutes provide the basis and rationale for the PBAC outcomes.

Requirements for listing a medicine on the PBS are outlined in Section 8. Applicants who are seeking PBAC reconsideration of a Recommendation are required to follow the processes outlined in Section 5.7.

7.1.2 Receipt of deferral of a recommendation

For deferrals of a recommendation by the PBAC, written advice (the PBAC Minutes) is provided to the applicant on Friday of week 22 of the PBAC cycle (five weeks after PBAC meeting).

The PBAC will defer making a decision where there is specific or missing information that cannot be obtained from the applicant and is required for PBAC decision-making (e.g. TGA delegate's overview or MSAC advice in relation to a codependent technology).

Applicants who receive a deferred outcome are not required to provide any further information for the subsequent PBAC consideration. Applicants will be advised of the outcome once the PBAC has received the required information and has made a decision.

7.1.3 Receipt of a decision to not recommend

Where the PBAC decides to not recommend a submission, written advice (the PBAC Minutes) is provided to the applicant on Friday of week 22 of the PBAC cycle (five weeks after PBAC meeting). This also provides the basis and rationale for the PBAC outcomes.

Applicants can meet with the PBAC Chair to:

- develop a greater understanding of the PBAC decision to not recommend a submission (see Section 7.1.4)
- discuss a PBAC nomination for a Facilitated Resolution Pathway (see Section 9.4)

Applicants may seek an independent review of the PBAC decision, if eligible (refer to Section 7.2).

Applicants choosing to lodge a resubmission are required to follow the processes outlined in Section 9.

7.1.4 Procedures for requesting a post-PBAC meeting with the PBAC Chair

Applicants who have received a decision to ‘not recommend’ may request a meeting with the PBAC Chair to develop an understanding of the reasons for the PBAC decision.

The PBAC Chair has the discretion to offer a post-PBAC meeting for positive recommendations. It is expected that this meeting would provide the applicant with additional context and information on the recommendation to enable the applicant to proceed to a pricing pathway. The PBAC Chair remains unable to change the recommendation of the PBAC.

Applicants should email the department to request a meeting (refer to Appendix A for contact details). The dates of these meetings are set in the [PBS calendar](#) and occur on Tuesday and Wednesday of week 23 (six weeks after the meeting).

Refer to Section 4.4 regarding attendees and conduct of the meeting. In addition to the PBAC Chair and the PBAC Deputy Chair, officers from OHTA may also attend as requested by the PBAC Chair.

Meetings are usually 30 minutes in duration. To assist with preparations for the meeting, applicants are requested to submit a one-page outline of the matters proposed for discussion at the meeting. The outline should include sufficient information to ensure the matters for discussion are clear. No new data will be considered or discussed. The PBAC Chair and departmental officers do not keep records of the issues discussed at the meeting.

7.2 Independent review

An independent review of a submission and the PBAC decision is available if the PBAC has declined to recommend the listing of a medicine/vaccine on the PBS/NIP or, in certain circumstances, if the PBAC has not recommended extending the listing of a PBS/NIP item for an additional indication.

The PBAC states in its Minutes if a submission is eligible for an independent review.

Details about the eligibility for, and the procedures undertaken in, the independent review are available on the [PBS website](#).

7.3 PBAC Outcomes

PBAC Outcomes are published to inform the public about the PBAC’s advice to the Minister for Health. The documents report the PBAC’s decisions in each case and summarise the reasons for the decision. These include PBAC decisions about submissions to list medicines/vaccines on the PBS/NIP, reports on currently listed medicines, general submissions from organisations and individuals, and other matters on the PBAC agenda.

7.3.1 Timeframe for publishing PBAC Outcomes

PBAC Outcomes are published on Friday of [week 23 of the PBAC cycle](#).

If a medicine has not completed the TGA review, the outcome will be withheld pending receipt of the TGA delegate's overview. After receiving this information, the outcome will be added to the outcomes for the respective PBAC meeting on the PBS website.

7.3.2 Preparing the PBAC Outcomes

Applicants preview the PBAC Outcomes, which are compiled from the ratified PBAC Minutes of the meeting by OHTA officers. The outcomes for each submission are forwarded to the applicant on Monday or Tuesday six weeks after the PBAC meeting.

For submissions with a not recommended or deferred outcome, the applicant has the opportunity to provide a comment to be published with the outcome statement. Applicants choosing to provide a comment are required to do so by Wednesday of week 23 of the PBAC cycle.

If the applicant believes that the PBAC Outcome has factual errors, the applicant can request that the PBAC Outcomes be revised.

The department will consider all requested changes before publishing the outcomes. As the outcome statement reflects the PBAC consideration, changes that substantially alter the wording of the decision or the intention of the PBAC will not be accepted by the department.

7.4 Public Summary Documents

Public Summary Documents (PSDs) inform the public of PBAC decisions and the basis for each PBAC outcome. This includes information on the clinical and cost effectiveness of medicines proposed for subsidy compared with alternative therapies (as required under the *National Health Act 1953*).

The following standardised approach to redaction processes supports the PBAC's commitment for greater transparency and consistency of information published in the PSD.

More information about the PSD structure is available on the [PBS website](#). PSDs conform to the Level AA accessibility requirement of the Web Content Accessibility Guidelines 2.0.

7.4.1 Steps to prepare and finalise PSDs

PSDs are based on the PBAC Minutes and applicants have a single opportunity to request redactions of information within the PSD prior to publication. See Section 7.4.3 for PSD publication timeframes.

The steps to prepare and finalise PSDs are as follows.

1. Departmental officers:
 - Replace the following with a standard range as outlined in Section 7.4.5:
 - Incremental cost-effectiveness ratios (ICERs) or other measure of the estimated cost-effectiveness.
 - Estimated numbers of patients and numbers of prescriptions dispensed.
 - Estimated financial (budget) implications of supplying the medicine/vaccine through the PBS/NIP.
 - Redact any related confidential financial and cost information within the PSD that is not clinical data, but is involved in generating any of these three types of estimates (including specific details of proposed risk sharing arrangements).

2. The department provides the proposed PSD to the applicant's designated contact or authorised representative by the end of week 27 following the PBAC meeting.
3. Within five business days, the applicant reviews the proposed PSD and, in writing, either:
 - confirms acceptance of the proposed PSD (and, for each instance where significant portions of data have been redacted by the department, the added descriptive paragraph to ensure the reader can understand the context of the redacted information) OR provides redaction and/or disclaimer and/or factual error requests to the department.
 - Refer to Section 7.4.4 for criteria for redactions of clinical data.
 - Redaction requests must include sufficient justification to support the request; further guidance on how to request redactions is at Appendix B – Supporting Guidance. Any request for a redaction that does not include a justification and meet the criteria will be rejected.
 - Where significant portions of data are requested for redaction, the applicant must also provide a descriptive paragraph in each case to ensure the reader can understand the context of the redacted information.
 - Refer to Section 7.4.6 for processes to request a disclaimer.
 - Refer to Section 7.4.7 for processes to address factual errors.
4. The department reviews any redaction requests received and notifies the applicant of the outcome by the end of week 31. Where further redactions are made and/or disclaimers added, the revised version of the PSD is provided to the applicant. Where a request for redaction is not accepted, the rationale for this decision is also provided to the applicant.

This version of the PSD is considered final and is published in accordance with the publishing timelines outlined in Section 7.4.3.

The applicant is provided the final version of the PSD prior to publication. Where the standard process is followed, this is two weeks prior to publication. Where an internal review is requested (see Section 7.4.2), this could be three business days prior to publication.

7.4.2 Internal review

If an applicant does not agree with the final version of the PSD, the applicant is able to request an internal review of the decisions made regarding the redaction request (maximum of one review per published PSD). The request must be made in writing within three business days of receiving the final version of the PSD and must include the following:

- Rationale for requesting the review, and
- Any additional evidence to support that review's delegate in making his/her final decision.

Where required, the review delegate (a senior officer to the officer who made the previous decision) may contact the applicant to discuss the review and redaction requests prior to making a decision.

The department provides the review decision and its rationale to the applicant prior to publishing the final PSD in accordance with the publishing timelines outlined in Section 7.4.3. Where the review results in changes to the PSD redactions, the department also provides an updated version to the applicant alongside this review decision.

7.4.3 Timeframe for Public Summary Document publication

The following table outlines the timeframes for preparing, finalising and publishing PSDs.

Week	Event	Responsible
17	PBAC Meeting (3 meeting cycles per year)	PBAC
20	PBAC Minutes to applicants with positive recommendations	Department
22	PBAC Minutes to applicants of all other submissions	Department
23	PBAC Outcomes published on PBS website	Department
27	Proposed PSDs provided to applicants with standardised redactions applied	Department
28	Applicants respond to proposed PSDs; provide any rationale and evidence to support any further redactions requested, and any descriptive paragraphs	Applicant
28-31	Any further redaction requests considered	Department
31	Finalised PSDs sent to applicants	Department
32	Applicants accept finalised PSDs or request an internal review	Applicant
32	Internal review undertaken (if required)	Department
33	For submissions recommended by PBAC for listing, and resubmissions to PBAC that were not recommended: <ul style="list-style-type: none"> any applicants that requested an internal review advised of outcome and provided with final PSD PSDs published on website 	Department
35	For initial submissions not recommended for listing, and deferrals: <ul style="list-style-type: none"> any applicants that requested an internal review advised of outcome and provided with final PSD PSDs published on website 	Department

For submissions made under the TGA–PBAC parallel process, PSDs for recommended or deferred items are prepared following standard timelines but are not published until TGA registration has occurred. PSDs for rejected items are prepared and published in accordance with the standard timeframes.

7.4.4 Redaction criteria – clinical data

The PBAC’s preference is for all clinical data relevant to its decision-making to be published. This includes clinical data that are not already in the public domain from any type of clinical study, and from any type of analysis within or across or derived from these clinical studies, and any alternative estimates from sources other than clinical studies. The release of the information considered by the PBAC aims to increase the transparency of its decision-making process.

The department considers redaction requests to clinical data under the following circumstances, where the data:

1. is from a clinical study for which no results at all would have entered the public domain at the time of publishing the PSD, and the applicant is able to demonstrate both that the publication

of the information in the PSD would prevent the publication of any results from this study elsewhere, and also that there is a documented requirement external to the applicant that these results (with or without other results) of the clinical study are to be published once they have been more completely generated.

- *This is to protect the ability for any results of this study to be published in a widely accessible publication.*

This criterion does not apply in the more common circumstance of where some/any results of a clinical study have already entered the public domain (for which, see the next criterion).

2. is included in a draft manuscript that has been submitted for publication in an identified journal and the applicant is able to demonstrate the publication of the information in the PSD would prevent publication in that journal.

- *This is to protect the ability for these specific results to be published in a widely accessible publication.*

This criterion only applies where the applicant has already submitted for journal publication (e.g. evidence of receipt of the submitted article by that journal). It does not apply where an applicant indicates that it intends to submit for journal publication at some stage in the future. The applicant also needs to provide evidence that the publication of data in the PSD would prevent publication in that particular journal. Such evidence may include providing the prospective journal's specific rules concerning pre-publication of data. Refer to the Supporting Guidance document at [Appendix B](#) for further information.

3. can be shown to potentially breach study participant confidentiality.

- *This is to protect the privacy of individuals within clinical studies.*

Any disclosure of confidential pricing information is avoided by including ranges in place of estimates in a published PSD (the types of estimates affected are specified in Section 7.4.5), therefore the department will not agree to a request for redaction of clinical data on the basis of seeking to avoid disclosing confidential pricing information.

Where a redaction is requested (refer to the Supporting Guidance document at [Appendix B](#) for further information), the applicant is required to provide a suitable description to replace the redacted information. The department finalises the description in the final version of the PSD. Where clinical data is redacted to allow its publication in a journal, the PSD identifies, at the place that the redaction occurs, the name of any identified journal to which the data has been submitted (criteria 1 or 2) or is proposed to be submitted (criterion 1).

7.4.5 Standard ranges for presenting economic and financial information in PSDs

Departmental officers replace relevant economic and financial information with the following standard ranges.

- a) ICER/QALY:
 - Dominant (i.e. cost saving and health improving),
 - \$0 to < \$5,000, then
 - \$10,000 increments to \$55,000, i.e. \$5,000 to < \$15,000, \$15,000 to < \$25,000, etc., then

- \$20,000 increments to \$155,000, i.e. \$55,000 to < \$75,000, \$75,000 to < \$95,000, etc., then
 - \$100,000 increments to \$1,055,000, i.e. \$155,000 to < \$255,000, \$255,000 to < \$355,000 etc., then
 - > \$1,055,000.
- b) Estimated numbers of patients (adding “per year” if estimating annual incidence rather than prevalence) or prescriptions dispensed in the utilisation information:
- < 500 (reflecting the Life Saving Drugs Program’s current definition of rare disease being a prevalence of 1 in 50,000 and an Australian population of 25 million),
 - 500 to < 5,000, then
 - 5,000 to < 10,000, then
 - 10,000 increments to 100,000, i.e. 20,000 to < 30,000, 30,000 to < 40,000, etc., then
 - 100,000 increments to 1,000,000, i.e. 100,000 to < 200,000, 200,000 to < 300,000, etc., then
 - 1,000,000 increments to 10,000,000, i.e. 1,000,000 to < 2,000,000, 2,000,000 to < 3,000,000, etc., then
 - > 10,000,000.
- c) Estimated financial implications (adding ‘per year’ if estimating annual implications rather than a combined estimate):
- net cost saving,
 - \$0 to < \$10 million, then
 - \$10 million increments to \$100 million, i.e. \$10 million to < \$20 million, \$20 million to < \$30 million, etc., then
 - \$100 million increments to \$1,000 million (\$1 billion), i.e. \$100 million to < \$200 million, \$200 million to < \$300 million, etc., then
 - > \$1 billion.

7.4.6 Disclaimers

Where specific clinical data has been provided specifically for the purposes of PBAC consideration, but it does not meet the criteria for a redaction request, the applicant may instead request that a disclaimer be included as a footnote to that specific data in the PSD to further inform the reader.

- *This is to enable the publication of this information, whilst ensuring that the applicant’s concerns of potential misinterpretation are suitably addressed.*
- *In these circumstances, the information will not be redacted; instead the following footnote will be applied to the paragraph, table or figure in which the clinical data is published in the PSD:*

** Note that the results presented in Paragraph X/ Figure X/ Table X are derived from ad-hoc/ post-hoc analyses conducted by the applicant/ during the evaluation/ by the ESC/ PBAC specifically for the purposes of informing the PBAC consideration. These analyses were not part of the pre-specified statistical plan for Study nnn-999. Interpretation of the results and their application should therefore be limited to seeking to understand the basis for the PBAC outcome and should not be used for any other purpose.*

The applicant is responsible for completing the details in each requested disclaimer and for submitting with (or without) any redaction requests.

7.4.7 Factual errors

If an applicant notices a factual error in the PSD, a request for correction should be sent to the department.

The applicant should request any correction within the five business days allocated for review of the proposed PSD after week 27 (along with any redaction and/or disclaimer requests if applicable).

Correction of any residual factual errors noticed in the final version of the PSD sent after week 31 must also be notified within three business days of receipt, however these usually should not require an internal review process for correction.

8 Procedures for a positive recommendation to list

Following a positive PBAC recommendation to list a medicine on the PBS schedule, there are several additional processes that must be completed before the medicine can be recommended to the Minister for Health for listing.

This includes:

- Completion of the Notice of Intent for Pricing Form (Part A of Application for Pricing Services). Refer to Section 8.2
- Lodgement of all documents required in the Pricing Offer Package. Refer to Section 8.3.
- Negotiation of a price and completion of a 'Request for approved ex-manufacturer price' form (PB11a) that reflects the price agreed in principle by the department. Refer to Section 8.3.
- Agreement on the expected utilisation and financial (budget) cost to the Australian Government. Refer to Section 8.5.
- Agreement of the restriction wording to be published on the PBS and RPBS schedule and in the listing instrument. Refer to Section 8.6.
- Establish a deed of agreement or other documentation related to a MAP, RSA and special pricing arrangement (SPA) if required. Refer to Section 8.7.
- Provision of a letter of application. Refer to Section 8.8.1.
- Assurance that the product will be available for supply on the date of listing. Refer to Section 8.8.2.
- Declaration of Responsible Person. Refer to Section 8.8.3.
- Application to list a medicine as a pharmaceutical benefit (PB11). This is provided in submission documentation. Refer to Section 5.
- Payment of all invoices issued as part of the listing process (from pre-submission fees to pricing fees) to enable a listing to occur.

Table 8.1 PBS listing steps responsibilities and timeframes

Week	Event	Responsible	Next step
17	PBAC – Wednesday to Friday of 1 st week of month 1.	PBAC	
18	Notification of PBAC outcome.	Department	
19			
20	Ratified PBAC Minutes to applicant for positive PBAC recommendations.	Department	
	Notice of Intent for Pricing form lodged through Part A of Application Form for Pricing Services – mandatory step to advise whether the applicant is proceeding to pricing services, returning to the PBAC for reconsideration or withdrawing from the process.	Applicant	Go / No Go
	Pricing offer package lodged through Part B of the Application Form for Pricing Services. The applicant must: (1) make a price offer (PB11a form); (2) provide pricing calculations or information to support price proposed in PB11a; (3) provide SPA request (if any); (4) agree in principle to the PBAC recommended deed; (5) confirm PBAC recommended restriction wording; (6) provide TGA approval letter; (7) update Utilisation and cost model ; and (8) provide signed Responsible Person form.	Applicant	
	Check for complete pricing offer package and utilisation and cost model format per website.	Department	Go / No Go
	In principle price agreement*	Department	Go / No Go
	Utilisation and cost model agreed; Deed terms agreed in-principle; and Restriction agreed in-principle.	Department/Applicant	Go / No Go
	Government processes begin: Deed signed by both parties; Restrictions finalised; No outstanding cost-recovery fees; and Listing 1st of each month. (up to 26 weeks in total for this step)	Department Department/Applicant Department/Applicant Applicant Department	

* A positive PBAC recommendation for which no acceptable price offer package was received within 6 months from when the applicant is issued the ratified PBAC Minutes, is deemed to be inactive for the purpose of seeking a PBS listing and will be recorded as inactive on the Medicine Status Website.

* In addition, if after 6 months from the date an applicant lodges their pricing offer package, there is no active negotiation between the applicant and the department, the department may cease to provide pricing services. If pricing services are ceased by the department, an applicant would be required to lodge a new Notice of Intent for Pricing form and pricing offer package to recommence negotiations with the department – refer to the Cost Recovery Administrative Guidelines for further information on this process.

This status is administrative only and does not impact on the PBAC's processes for reconsidering or rescinding positive recommendations which are not yet implemented.

Unless otherwise stated, items that are available on the PBS are also available on the RPBS, and references to the PBS in this section should be taken to include the RPBS.

8.1 Pricing pathways

There are five different pricing pathways to progress a positive PBAC recommendation.

Pricing pathways do not usually apply to generic medicines (refer Section 5.8) or the post-PBAC processes for vaccines submissions to be listed on the NIP (refer Section 8.10).

Pricing Pathway A requires the PBAC to recommend that it is appropriate for a submission to follow this pathway. All other pricing pathways are determined based on the listing arrangements required. Applicants nominate their pricing pathway via the Notice of Intent for Pricing form.

Pricing Pathway A - Facilitated

The PBAC will determine whether a submission is eligible for Pricing Pathway A as part of its recommendation. A high-level outcome of the PBAC's advice is provided to the applicant one week after the meeting via email including if Pathway A applies. For applications that are recommended, details of the PBAC's advice will be included in the PBAC Minutes received by the applicant in the third week after the PBAC meeting.

Pricing Pathway A can apply for submissions where the PBAC considers that:

- the medicine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies; and
- the medicine addresses a high and urgent unmet clinical need; and
- it would be in the public interest for the submission to be recommended to follow this pathway

In relation to the public interest component of the criteria, the PBAC will have regard to whether it is likely that the interests of the Australian public will be advanced by the recommendation being progressed via Pricing Pathway A, noting that the submission must also meet the first two criteria.

An applicant will either accept the PBAC's Pricing Pathway A recommendation or nominate another pricing pathway via the Notice of Intent for Pricing form.

A Case Manager will be assigned where the applicant has accepted the PBAC's recommendation for Pricing Pathway A. Refer to Section 8.1.1.

Pricing Pathway B – New deed

Pricing Pathway B 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.

Pricing Pathway C – Existing deed

Pricing Pathway C 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 arrangements, whether these relate to the new listing or to another existing listing. Where required, the deed's original responsible person(s) will be notified of the provision of information to the new applicant. Refer to Section 8.1.2 for additional guidance.

Pricing Pathway D – No deed

Pricing Pathway D applies to submissions which do not involve negotiation of a new or existing deed of agreement.

Secretariat pricing

The secretariat pricing pathway applies to changes to listings of existing medicines which do not require a new price.

8.1.1 Case Manager

Where the applicant has accepted the PBAC recommendation for Pricing Pathway A via lodgement of the Notice of Intent for Pricing form, a Case Manager is assigned to facilitate communication and information sharing between the department and applicant (and other authorised agents as required) during the negotiation phase.

The role of the Case Manager is to ensure applicants are aware of the requirements and timeframes relating to their submission, and that applicants are provided with the necessary information for meeting these requirements in a timely manner. While Case Managers will support the overall administrative process, Case Managers will not facilitate, co-ordinate, or act as an intermediary in negotiation processes.

As decisions on the date of PBS listing remain a matter for Government, Case Managers will not be in a position to advise applicants about potential or actual listing dates.

8.1.2 Existing deed arrangement

When the applicant enters into the same therapeutic market as an already listed medicine (Pricing Pathway C) that is subject to a confidential deed of agreement, the applicant will be required to make confidentiality undertakings before any confidential details of the deed of agreement, for example a hidden price, are released to the applicant. This confidentiality process enables applicants to have access to information required to determine if they would like to submit a Notice of Intent for Pricing form. The applicant can choose to execute this step before they submit a Notice of Intent for Pricing form, or in parallel with the Notice of Intent for Pricing process.

The applicant initiates the Deed of Confidentiality process by contacting the department's PBS Pricing and Managed Access Section (refer to contact details in Appendix A) to request the confidential effective price. This may be done any time after the ratified PBAC Minutes are provided to the applicant. If the PBAC recommendation is not yet public, the applicant will need to grant permission to the department, to allow the department to inform the responsible person of the comparator medicine about the new PBAC recommendation.

The department will then prepare a Deed of Confidentiality for the applicant requesting the confidential effective price.

The department will provide the Deed of Confidentiality within 3–5 business days after it receives the request. Once the Deed of Confidentiality is executed, the department can provide the applicant with the effective price and other relevant information.

This process enables applicants to have all available information to help them determine if they would like to proceed to pricing negotiations prior to lodging the Notice of Intent for Pricing form.

8.2 Notice of Intent for Pricing

The Notice of Intent for Pricing form ([Part A of the Application Form for Pricing Services](#)) is mandatory for all submissions that receive a positive PBAC recommendation.

The earliest opportunity for an applicant to submit their Notice of Intent for Pricing form is week 4 following a positive PBAC recommendation. The form is to be submitted to PBS Pricing (refer contact details in Appendix A). The department will reply within one business day to confirm receipt of the form.

The completed Notice of Intent for Pricing form will advise the department that:

- the applicant intends to submit a pricing offer package and, if so, the expected timing of this offer (within the required 5-30 business day timeframe) and, ideally, confirmation of a date for which supply of the medicine will be available in Australia; or
- the applicant intends to return their submission to the PBAC for reconsideration (refer 5.7); or
- the applicant does not intend to submit a pricing offer package (which would be recorded as withdrawing from the listing process); and
- for submissions with PBAC advice to support the Pricing Pathway A option, whether the applicant accepts the recommendation of Pricing Pathway A.

If an applicant does not lodge a Notice of Intent for Pricing form within 60 calendar days of being issued the ratified PBAC Minutes the submission will be deemed 'inactive' for data collection and reporting purposes. This status is administrative only and does not impact on the PBAC's processes for reconsidering or rescinding positive recommendations which are not yet implemented.

8.3 Pricing offer package

A complete pricing offer package will ensure a medicine's listing can progress expeditiously from the point of offer. Applicants submit their pricing offer package by completing [Part B of the Application Form for Pricing Services](#).

A pricing offer package or request for price negotiations will not proceed if the Notice of Intent for Pricing form has not been submitted. The only exception is if the department decides that progressing the application is necessary to address an urgent public health need.

Applicants are able to submit their pricing offer package within a minimum of five business days and a maximum of 30 business days after lodgement of the Notice of Intent for Pricing form. If the pricing offer package is not received within 30 business days, applicants will be required to lodge a new Notice of Intent for Pricing form. The earliest opportunity for applicants to submit a pricing offer package would be in week 5, which would generally facilitate a reduction in the overall time to listing.

The pricing offer package must include:

- a complete [PB11a form](#) ('Request for approved ex-manufacturer price')
- pricing calculations or information to support price proposed in the PB11a;
- a special pricing agreement (SPA) request (if any, refer to [SPA criteria](#) for further details);
- agreement in principle to any PBAC advice on deed arrangements;
- confirmation of PBAC recommended restriction wording;
- TGA approval letter;
- updated utilisation and cost model (refer to [PBAC website](#) for further information); and
- completed and signed [Responsible Person form](#) (refer to Section 8.8.3), which includes the authorised representative(s).

Where an applicant is requesting a waiver or exemption, the [PB11b form](#) could be included to support this request. Guidance on how to submit a waiver application is included in the [Cost Recovery Administrative Guidelines](#).

An incomplete pricing offer package will not progress further until the missing information is provided by the applicant. If the department rejects the applicant's pricing offer (pb11a form), the department will provide information as to why the offer was rejected. The level of detail included in the rationale will be based on the quality of information in the pricing offer package.

Once the department has confirmed the pricing offer package is complete and includes all of the required components (within 3-5 business days), the department and applicant will commence negotiation of the terms of listing (refer to Section 8.4).

8.3.1 Cost of goods (PB11b)

A completed and signed 'Cost of goods information' ([PB11b](#)) form for the medicinal product proposed for listing is required at the time of submission to the PBAC (refer to Section 5).

8.4 Negotiation and agreement

Where the applicant and department work together regarding the terms of the listing within the parameters of the PBAC's recommendation.

This step commences once the department has confirmed the submitted pricing offer package is complete and ends when there is agreement to the terms of the listing. The negotiation and agreement step includes the following:

- negotiation of a price
- negotiation of the expected utilisation and financial (budget) costs. Refer 8.5 Finalisation of budget impact for more information
- negotiation of a deed of agreement or other documentation relation to a Managed Access Program, risk share arrangement and special pricing arrangement (if required); and
- finalisation of proposed restriction wording. Refer 8.6 Restriction Wording for more information.

Once negotiations have been agreed in-principle between the applicant and the department, the applicant is required to update the PB11a form as necessary and provide a signed copy to the department by email or post (refer to contact details in Appendix A).

Once this step has occurred, government processes can commence whilst the department and the applicant finalise the following in preparation for listing:

- Deed of Agreement (if applicable) to be signed by both parties;
- Restriction wording finalised; and
- all outstanding cost recovery fees are paid.

Where an applicant has not actively pursued a price negotiation for 6 months, the proposed listing will be considered inactive for reporting and data collection purposes.

Where an applicant has not actively pursued a price negotiation, after 6 months from the date an applicant lodges their pricing offer package, the department may cease to provide pricing services.

MSW reporting or ceasing pricing services does not impact on the PBAC's processes for reconsidering or rescinding positive recommendations which are not yet implemented.

8.5 Finalisation of the budget impact

The PBAC considers [Section 4 - Use of the medicine in practice in the PBAC Guidelines](#) in submissions to list medicines/vaccines on the PBS/NIP. Following a positive recommendation, the estimates of use are reviewed by departmental officers to check that each component of the estimates of use and costs would be correct at the expected time of listing and reflect the PBAC recommendation to the Minister. These officers also review the [Utilisation and cost model](#) structure and inputs to ensure this is accurate and complete.

The utilisation and cost model of use through the PBS and the RPBS is provided to each applicant of the medicine for review, comment and clarification. The applicant is required to agree to the estimates of use and costs. Where an applicant is unable to agree to the estimates of use and cost, the listing process will stop and a further submission to the PBAC may be required.

Finalisation of the agreed utilisation and financial impact requires an email from the applicant documenting agreement of the:

- requested price (including published price if applicable)
- utilisation and cost model supporting estimates of use and financial impact

Following the applicant's agreement, the utilisation and cost model is circulated to other areas of the department (e.g. Medical Benefits Division) and other affected government agencies.

If the listing is subject to an RSA or MAP, the agreed estimates form a basis for these arrangements (refer to Section 8.4).

8.5.1 Review of budget impact

The department reviews estimates of use and costs following the PBAC's recommendation. The reviewed utilisation and cost model is provided to applicants.

Applicants are given up to five business days to review and comment on the estimates of utilisation and financial impact. If an applicant believes there are errors in the model, there is an opportunity to discuss the model with the department. Any substantial revision may require a new submission to the PBAC.

The department will check the model has been provided in the correct format. The department will not accept utilisation and cost models that do not comply with the format specified on the [PBAC website](#). Where the applicant believes that the standard template provided on the PBAC website is insufficient to complete the costing, additional calculations can be added, however any substantive change to the template should be discussed with the PBS Estimates team (refer to contact details in Appendix A). Failure to provide costings in the required format will lead to delays. The department will undertake compliance checks and advise the applicant within 3-5 business days whether the utilisation and cost model can progress to content assessment.

Following agreement of the estimates of utilisation and financial impact between the departmental officer and the applicant, the other affected divisions of Health and portfolio agencies are approached to review the costs. A finalised cost to the Australian Government is considered by the Department of Finance. This finalised cost is included in the recommendation to list to the Minister for Health.

8.5.2 Budget impact timeframes

The financial impact of all listings on the PBS and the RPBS are considered by each responsible area of the Australian Government. The Minister for Health will also consider costs in relation to the Medicare Benefits Schedule, Services Australia and any other area affected by a listing on the PBS and the RPBS schedules. Where the net cost to the Australian Government of listing a medicine is greater than \$20 million in any of the forward years, the Minister refers the listing to the Cabinet for consideration. Refer to Section 4 of the PBAC Guidelines for further details of the requirements for estimating budget impact.

Refer to Appendix A for contact details.

8.6 Finalisation of restriction wording

The PBAC is required, as part of its advice to the Minister, to recommend the circumstances under which a medicine should be supplied under a new or amended PBS listing. These circumstances are referred to as a restriction. The wording of the restriction must be finalised before the Minister can approve the medicine for listing on the PBS.

The final restriction will generally be provided to the applicant in the PBAC Minutes, three weeks after the PBAC meeting.

When the restriction is complex, the PBAC Minutes will indicate the restriction wording is 'to be finalised'. The department's Restrictions Working Group may meet to discuss the wording to ensure it reflects the intention of the PBAC. The applicant may be approached for comment on the restriction by the department.

Departmental officers, working with the Restrictions Working Group and the PBAC out-of-session, continue development of the restriction within the intent of the PBAC recommendation. Where appropriate, clinical specialists may be consulted (refer to Section 6.8). Once the restriction is drafted; Services Australia reviews the restriction and advises of any issues that may arise with

administration. The completed draft is provided to the applicant for information purposes prior to entry into the PBS.

If the applicant does not agree with the finalised restriction, the listing will not proceed and the medicine will not be available on the PBS. Where the department and the applicant are unable to resolve differences about the restriction, the listing will not proceed. If the issues require PBAC consideration, the applicant will need to lodge a new submission (see Section 5). Refer to Appendix A for contact details.

8.7 Preparation and finalisation of additional access arrangements

The PBAC's advice to the Minister may include specific comment if it considers that some elements of the evidence are not strongly convincing or that the government should take actions to ensure access is limited to the cost-effective population, or to otherwise limit unjustified financial expenditure or obtain additional evidence for a future review.

Applicants and the Australian Government may negotiate an RSA or a MAP after the PBAC has made its recommendation. Where a comparator medicine has an existing RSA, it is government policy that single brand medicines entering the same therapeutic market are also included in the existing RSA. Examples of this include sharing a cap on government expenditure across a number of medicines.

The majority of RSAs and MAPs are supported by deeds of agreement between the responsible person (as defined in the *National Health Act 1953*) and the department.

8.7.1 Procedure for preparation of deeds of agreement

Based on the advice in the PBAC Minutes, the department prepares a draft deed of agreement, based on the standard template on the [PBS website](#). This draft is provided to the applicant as soon as possible after the estimates of utilisation and financial impact have been considered by the Department of Finance. Where the applicant enters into the same therapeutic market as an already listed medicine, the applicant will be required to make confidentiality undertakings prior to a draft Deed being provided.

This draft deed of agreement is forwarded by email to the responsible person. The applicant has up to 10 business days to respond. If more time is required, an extension can be requested by email to the contact officer in the department.

The standard clauses in the deed of agreement will not be amended unless the attributes of a particular arrangement associated with a medicine are identified by the PBAC as requiring different treatment, or the Australian Government delegate determines that the change is necessary based on an identifiable detriment to the applicant.

The deed of agreement must be completed and signed at least six weeks before the date the medicine is proposed to be listed on the PBS.

Negotiation of financial-based agreements are based on the finalised financial estimates (refer to Section 8.2).

All documents are handled in accordance with the Australian Government's standards for confidentiality and transparency (see Section 3).

Where the operation of the deed results in monies being owed to the Australian Government, all invoices are raised by the department and forwarded to the applicant. The accompanying letter will provide additional documentation explaining the basis for the monies owing and the date monies are due.

8.7.2 Revision of deeds and other useful information

The department reviews all deeds at the end of the term of the deed or following a recommendation by the PBAC that affects the operation of the deed. Deeds can be lapsed or renewed following a review.

The department may seek advice about a deed from the PBAC or, through the PBAC, from DUSC or ESC. The department will email the applicant, advising them of the outcomes of any review of the deed.

If applicants have concerns about the operation of a deed, there is a dispute resolution mechanism included in the deed.

Refer to Appendix A for contact details.

8.8 Other listing documents required

The department requires additional listing documents to have the medicine listed on the PBS Schedule. The deadlines for these documents are provided on the [PBS website](#).

These documents are forwarded to the department by email (refer to contact details in Appendix A).

8.8.1 Letter of application (where applicable)

Where the medicinal product has not been listed on the PBS, the department requires an application letter to be provided by the applicant. The letter of application should be signed by the responsible persons authorised representative and contain or include:

- an application to list a medicine or medicinal product as a Pharmaceutical Benefit (form PB11) if this has not already been provided in the submission
- in the case of listing a brand containing a drug on F2, or drug that will move to F2 on the new brand listing day, any comments an applicant wishes to provide to the delegate for consideration of whether to make an originator brand determination under s99ADB of the *National Health Act 1953* (see Sections 5.5 and 5.7)
- a hyperlink to the TGA-approved Product Information for the medicinal product
- an assurance of supply (stock assurance - see Section 8.8.2)
- a responsible person form (see Section 8.8.3)

For contact information, refer to Appendix A.

8.8.2 Assurance of supply

A new medicinal product should be available for ordering by pharmacies, hospitals or other PBS dispensers so that the product can be 'in stock' for dispensing on the first date of listing on the PBS. The cover letter must include an undertaking that sufficient stock of the product to meet demand

will be available to allow for delivery to PBS dispensers (e.g. pharmacies, hospitals or other suppliers) in time for the PBS listing day.

Separate to the assurance of supply, brands may be affected by the guarantee of supply provisions in Division 3C of Part VII (ss99AE–99AEL) of the *National Health Act 1953*. These are intended to deter suppliers from entering the Australian market without a viable business model able to support their long-term participation in the market.

Where applicable, the guarantee of supply applies from the date of listing of the product on the PBS Schedule. Additional details, including the period for which the guarantee provisions apply, are found on the [PBS website](#).

8.8.3 Responsible Person

The Responsible Person is the person or corporation with a registered ABN or ACN that is the supplier of a particular brand of a medicine on the PBS.

A Responsible Person has responsibility under the *National Health Act 1953* for:

- price negotiations and agreements (s85AD)
- price disclosure (Division 3B)
- guarantee of supply (Division 3C)

The Act provides for penalties and other sanctions, which may apply if the Responsible Person fails to meet the price disclosure and guarantee of supply obligations.

The OHTA requires a completed [Responsible Person form](#), which includes the nomination of an authorised representative, for each product to be listed on the PBS.

Further information can be obtained from the department (refer to contact details in Appendix A).

8.9 Notification of listing on the PBS

The Department cannot confirm the date of listing, as even after the Department and the applicant have agreed the price and financial impact as the actual listing date is subject to agreement with other Government Agencies and is ultimately a decision of the Australian Government.

Approximately two weeks prior to the effective date, the nominated [Authorised Representative](#) will receive a notification from the Supplier Update System which contains the Summary of Changes relevant to the particular [Responsible Person](#).

The Summary of Changes includes a notification of the new listing, the item code that the new item will be listed under and other details regarding the prescribing requirements for the new item. The timing of this notification is dependent on the requisite agreements being in place.

8.10 Listing a vaccine on the NIP

Where the PBAC makes a positive recommendation to list a new vaccine on the NIP or vary the conditions for a current vaccine on the NIP, and the price has been agreed in principle, Population Health Division will seek approval from the Australian Government to fund the vaccine under the NIP.

Where a new or amended listing is approved by government, Population Health Division will amend the National Health (Immunisation Program-Designated Vaccines) Determination to include the new or amended listing.

Population Health Division conducts tenders to procure the supply of vaccines through the NIP. To participate in a tender process, a vaccine must have received a positive PBAC recommendation before the tender closing date, and be listed on the Determination before contract execution.

All inquiries for listing vaccines on the NIP should be referred to the ATAGI Secretariat. For contact information, refer to Appendix A.

9 Procedures for submissions not recommended

All applicants with a 'not recommended' PBAC outcome are able to lodge a resubmission via the Standard Re-entry Pathway.

Based on the PBAC's independent assessment of the level of additional information required and issues to be addressed before further PBAC consideration, the PBAC may nominate an Early Resolution, Early Re-entry or Facilitated Resolution Pathway. Should the applicant not accept the PBAC nominated resubmission pathway, but still wish for further PBAC consideration, the Standard Re-entry Pathway applies.

The PBAC will nominate a resubmission pathway based on the PBAC's independent assessment of:

1. the issues for resolution; and
2. whether the medicine or vaccine represented High Added Therapeutic Value (HATV) for the proposed population:
 - the medicine or vaccine addresses a high and urgent unmet clinical need; and
 - the medicine or vaccine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

Once an applicant is advised of a PBAC decision not to recommend and has received the PBAC Minutes, an applicant lodging a resubmission is required to:

- Lodge an Intent to Apply Form (Refer Section 9.2).
- Lodge the Resubmission (Refer Section 9.3).

9.1 Resubmission pathways

There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC (refer Section 5.7 for procedures to request PBAC reconsideration of a recommendation).

Standard Re-entry Pathway

The Standard Re-entry Pathway is the default pathway for resubmissions, including where the PBAC did not nominate a resubmission pathway. The Standard Re-entry Pathway also applies where:

- an applicant chooses not to accept the PBAC nominated resubmission 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
- an applicant decides to lodge their resubmission later than the allowable timelines for the other pathways; or

- an Early Re-entry, Early Resolution or Facilitated Resolution Pathway resubmission receives a 'not recommended' outcome.

Early Re-entry Pathway

An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. This would include circumstances where:

- new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and
- a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission.

Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting (Refer Section 9.2 and 9.3).

Where an applicant chooses not to accept the PBAC nominated pathway; addresses additional issues; or is unable to meet the lodgement timeframes, the Standard Re-entry Pathway would apply.

Early Resolution Pathway

The PBAC may nominate an Early Resolution Pathway where the PBAC considers that the remaining issues could be easily resolved, including when:

- new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and
- a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission.

and where the medicine or vaccine meets the HATV criteria:

- the medicine or vaccine addresses a high and urgent unmet clinical need; and
- the medicine or vaccine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.

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.

Facilitated Resolution Pathway

A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop and where the medicine or vaccine meets the HATV criteria:

- the medicine or vaccine addresses a high and urgent unmet clinical need; and
- the medicine or vaccine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

Applicants who accept this pathway are eligible for a solution-focused workshop with one or more members of the PBAC (refer Section 9.4 for further details). It is expected that Facilitated Resolution Pathway resubmissions will require evaluation of a new and/or updated model structure and/or input variable changes beyond those specified by the PBAC to support the economic claims or estimate the utilisation and financial impact in the resubmission. This may also include other substantial changes from the previous submission that require re-evaluation.

Applicants will need to request a post-PBAC meeting with the PBAC Chair (see Section 7.1.4) to finalise the workshop agenda, required attendees and to discuss any other matters required to prepare for the workshop.

Where an applicant chooses not to accept the PBAC nominated pathway; addresses additional issues; or is unable to meet the lodgement timeframes, the Standard Re-entry Pathway would apply.

9.2 Intent to Apply – resubmission pathways

The HPP is the approved method for lodging an Intent to Apply form which is mandatory for all submissions lodged for PBAC consideration. This form must be lodged as follows:

Table 9.2.1 Timeframe for Intent to Apply lodgement

Resubmission Pathway	Timeframe
Early Re-entry Pathway	At least 5 business days prior to the submission due day
Early Resolution Pathway	At least 5 business days prior to the submission due day
Facilitated Resolution Pathway	At least 10 business days prior to the workshop* being held
Standard Re-entry Pathway	At least 20 business days prior to the submission due day

*Facilitated Resolution Workshop dates will be scheduled on a case-by-case basis – refer to Section 9.4.

Once the Intent to Apply form is submitted, applicants cannot change the information in the form. If the applicant has made a minor administration error (for example, an error in the contact details), the applicant must email the PBAC Secretariat about the error so they can update the information.

A resubmission will not proceed to the PBAC if an Intent to Apply has not been submitted by 5pm AEDT, on or by the due date (lodgement dates are available on the [PBS calendar](#)).

As outlined in Section 5.1, the only exception is where the department determines that progressing the application is necessary to address an urgent public health need (refer section 30 of the Cost Recovery Regulations).

9.3 Lodging a submission for a resubmission pathway

9.3.1 Timelines for lodgement

The following timelines apply for resubmission pathways:

Table 9.3.1 Timeframe for resubmission lodgement

Resubmission Pathway	Timeframe
Early Re-entry Pathway	Friday week 7 of the current or next PBAC meeting cycles only
Early Resolution Pathway	Friday week 7 of the current or next PBAC meeting cycles only
Facilitated Resolution Pathway	Wednesday week 0 following the workshop of the next or following PBAC meeting cycles only*
Standard Re-entry Pathway	Wednesday week 0 of any PBAC meeting cycle

*Please note: a submission can only be lodged after the workshop has been held (see Section 9.4). The submission can be lodged in week 17 or week 34.

9.3.2 Documents required in submission

The following requirements apply to lodging a submission via all resubmission pathways:

- Sections 5.2 Lodging a submission and 5.3 Compliance with standard IT capability.
- Early Re-entry and Early Resolution Pathway submissions will require the same documents as a Category 3 and 4 Submission as outlined in Section 5.5. Applicants are also required to include a fully executable Section 3 model containing the specific change(s) requested by the PBAC and their consequences for the model's results.
- Facilitated Resolution Pathway submissions are expected to require the same documents as a Category 1 and 2 Submission as outlined in Section 5.4.
- For a Standard Re-entry Pathway submission, the applicant is required to provide the documents required based on the request included in the submission.
 - For example, where the resubmission relates to a request for PBS listing of a new indication of a currently listed medicine, the requirements for a Category 2 submission apply (refer Section 5.4).
 - Where the submission relates to a change to an existing listing that does not change the population, the requirements of a Category 3 submission apply (refer Section 5.5).

9.3.3 Confirmation of Early Re-entry or Early Resolution Pathway consideration

Once an Early Re-entry Pathway or Early Resolution Pathway submission has been lodged, the department will confirm that the submission addresses only the issues identified by the PBAC.

If the submission includes additional information than what was requested by the PBAC, applicants will be advised within 4 weeks of lodgement and will have the following options:

- continue with the submission as lodged for consideration at the intended PBAC meeting; or
- withdraw the submission and resubmit through the Standard Re-entry Pathway at the next submission due day.

If the applicant chooses to proceed, the PSD will reflect the applicant's choice and the rationale for the PBAC's decision.

9.4 Facilitated Resolution Workshop

Where the applicant has accepted the PBAC's nomination for a Facilitated Resolution Pathway, details of the workshop will be advised electronically by the department. Facilitated Resolution Workshop dates are scheduled on a case-by-case basis.

The workshop provides an applicant with the opportunity to meet with one or more members of the PBAC to explore feasible options to address the issues identified by the PBAC in the Minutes.

The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair. Applicants must provide supporting material at least five business days prior to the workshop to support discussion. This includes the Facilitated Resolution Pathway Workshop Briefing Paper. All agenda and supporting material are treated as in-confidence until the standard PSD redaction rules apply (refer Section 7.4 Public Summary Documents).

Applicants should note the following:

- Workshops will be a maximum of 3 hours in duration.
- Workshop attendees should be discussed and agreed at the post-PBAC meeting with the Chair. The applicant must ensure at least one attendee has the authority to make decisions on behalf of the company as a whole regarding the feasibility of any option(s) being explored to address PBAC's issues for resolution (in accordance with the workshop agenda).
- An applicant's decision to participate in a workshop does not influence the PBAC's considerations of the submission, and does not guarantee that the submission will result in a PBAC recommendation.
- Any advice provided by members of the PBAC, the applicant or the department in a workshop is in no way binding on the PBAC, the department, applicant, evaluation groups or sub-committees of the PBAC.
- Applicants must form their own judgments about how to use the explorations of the workshop and any advice provided during this workshop in the development of the submission.
- It is recommended that all applicants, including those that have attended a Facilitated Resolution Pathway workshop, should consult the PBAC Guidelines when preparing their submission.

The record of the workshop outcomes is the responsibility of the applicant and must be completed using the template provided by the department. This record should capture the developments of the workshop on each of the matters identified for discussion by the PBAC in its Minutes.

Applicants are required to return this record to the department within 10 business days following the workshop. The department will review the record, and confirm the main discussion points or provide information about discrepancies within 10 business days of receipt. The record will then be considered final. Applicants should note that the department's response to the record remains non-binding, and that the record is not an opportunity to seek additional advice.

9.5 Resubmission requirements and procedures for consideration of resubmissions

The HPP will guide applicants to provide the required resubmission documents. The PBAC will utilise the subcommittees for resubmissions as required to assist PBAC reconsideration. The role of the PBAC and PBAC subcommittees is outlined in Section 6.

Table 9.3.1 Resubmission requirements and evaluation processes

Resubmission Pathway	Resubmission requirements	Resubmission evaluation
Early Re-entry Pathway	Same as for a Category 3 submission.	Includes Submission Overview.
Early Resolution Pathway	Same as for a Category 3 submission.	Not required due to out-of-session consideration.
Facilitated Resolution Pathway	Same as for a Category 2 submission.	Includes submission Commentary, ESC and/or DUSC advice provided on a case-by-case basis.
Standard Re-entry Pathway	Dependent on the request in the resubmission: Same as for a Category 2 submission; OR Same as for a Category 3 submission.	Includes submission Commentary, ESC and/or DUSC advice provided on a case-by-case basis; OR a submission Overview dependent on the request in the resubmission.

Sections 6.2 Evaluation of Submissions, 6.4 Input of the applicant into the PBAC consideration, 6.6 Role of the Nutritional Products Working Party, 6.7 Consumer input, 6.8 Additional clinical input, 6.9 PBAC and subcommittee members attending other meetings, 6.10 Stakeholder meetings and 6.11 Co-dependent submission processes apply as required.

Resubmissions are unlikely to be proceeding via parallel processing (refer Section 6.3). It is expected that ATAGI advice would only be required in relation to any new information provided as part of a resubmission (refer Section 6.5).

For Facilitated Resolution Pathway and certain Standard Re-entry Pathway resubmissions (dependent on the request), applicants have two opportunities to provide written input, the pre-subcommittee response (refer to Section 6.4.1) and the pre-PBAC response (refer to Section 6.4.2), and one opportunity to present comments to the PBAC in the form of a hearing (refer to Section 6.4.3).

For Early Resolution Pathway, applicants have no opportunity to respond further due to early consideration. For Early Re-entry Pathway, applicants have one opportunity to provide written input, pre-PBAC response (refer to Section 6.4.2).

9.6 Post-PBAC procedures for applicants

Consistent with Section 7.1, the following timeframes apply for notification of PBAC outcomes for resubmissions.

Table 9.6.1 Timeframe for notification of PBAC outcomes*

Timeframe	PBAC outcome provided
One week after PBAC reconsideration	Emailed advice of type of PBAC outcome including any PBAC nominated pathways (recommended and not recommended submissions)
Three weeks after PBAC reconsideration	Ratified PBAC Minutes for positive recommendations by email (Section 7.1.1)
Five weeks after PBAC reconsideration	Ratified PBAC Minutes for deferred and not recommended submissions by email (Sections 7.1.2 and 7.1.3)

*For Early Resolution Pathway resubmissions considered out-of-session, the same communication timelines apply; anchored to the date of PBAC reconsideration (i.e. email advice of PBAC outcome one week after out-of-session PBAC consideration, and ratified Minutes provided either three or five weeks after PBAC reconsideration dependent on the outcome.

10 Review of PBS listings

The PBAC and the Minister can request reviews of medicine use, cost-effectiveness and other aspects of quality use of PBS-listed medicines. This includes post-market reviews (see Section 10.2), cost-effectiveness reviews, and reviews of the utilisation of specific medicines or groups of medicines listed on the PBS.

10.1 Drug Utilisation Sub-Committee review

DUSC has a role in reviewing PBS-listed medicines (see Section 6.1.3)

10.1.1 Drug Utilisation Sub-Committee review process and timeframes

DUSC regularly reviews the PBS Schedule for medicines that have been listed for 24 months. DUSC selects individual medicines or groups of medicines to be reviewed. DUSC may also undertake 'ad hoc' reviews as requested by the PBAC or the Minister. The applicant is informed of the review after the meeting.

Planned reviews are listed in the outcomes of the DUSC meeting, which are published on the PBS website. Applicants are notified at least ten weeks before a DUSC meeting if a report on the use of a medicine they applicant will be considered.

Applicants are provided with the DUSC reports on the utilisation of medicines four weeks before the DUSC meeting (PBAC week 8). Each applicant has two weeks to provide a written response to the department (DUSC Secretariat) if they choose. Responses must be provided to the department by close of business on the Wednesday of week 10 of the PBAC cycle. Refer to Appendix A for contact details.

DUSC considers the report in conjunction with any responses received from applicants and other relevant stakeholders at the DUSC meeting.

Each applicant is provided with a copy of the DUSC Minutes prepared following DUSC consideration.

Advice to the PBAC

The report, stakeholder responses and DUSC Minutes are referred by DUSC to the PBAC for noting or consideration. DUSC may provide specific advice for PBAC to consider.

A list of DUSC reports on the utilisation of PBS medicines to be considered by the PBAC are published on the PBS website 10 weeks before the date of the PBAC meeting. Consumers are invited to make comments that are submitted directly to the department (see Section 6.7.1).

The PBAC meeting occurs five weeks after the DUSC meeting. The PBAC can make a number of different recommendations to the Minister after it considers the DUSC reports, including, but not limited to:

- revising the restriction wording
- revising the category of the listing or type of approved prescriber
- requesting DUSC to revise the utilisation report, as specified by the PBAC

- requesting further consultation
- advising the Minister for Health that a post-market review is warranted (refer to Section 10.2)

Each applicant receives a copy of the PBAC Minutes following the PBAC consideration of DUSC advice and reports for their medicine.

10.1.2 Publication of DUSC reports

The DUSC public release documents provide public access to DUSC utilisation analysis reports.

Applicants are given the opportunity to provide a short comment for publication with the report. Applicants may also request information they consider commercially sensitive to be redacted.

The DUSC public release document is sent to each relevant applicant 15 weeks after the DUSC meeting. Applicants have two-and-a-half weeks to review the public release document and provide comments to the DUSC Secretariat. Within the next three weeks, there may be further negotiation on wording between the Secretariat and the applicant depending on the nature of the proposed comments and redactions. The Secretariat provides the finalised public release document to the applicant at the end of the three weeks. The DUSC report is published on the PBS website two weeks later.

10.2 Post-market Reviews

The Australian Government has introduced a systematic approach to monitoring and reviewing the ongoing safety, effectiveness and cost-effectiveness of medicines listed on the PBS.

Post-market reviews of PBS-listed medicines are conducted under the 2011–12 Budget measure – *‘Improving sustainability of the Pharmaceutical Benefits Scheme (PBS) through enhanced post-market surveillance’*. They fall under the quality use of medicines objective of the National Medicines Policy framework. This includes promoting the ongoing safe and effective use of medicines, with the aim to improve health outcomes for all Australians.

These reviews aim to:

- improve patient safety through better understanding of adverse events and medicine-related harms
- ensure the ongoing viability of the PBS through targeted medicines usage, and avoiding preventable wastage or inappropriate prescribing
- develop a better understanding of medicines use, to review intended clinical benefit and inform medicines evaluation processes
- ensure ongoing cost-effectiveness, including through better management of clinical and economic uncertainty
- achieve overall improvements to the quality use of medicines and education for patients and prescribers

The Australian Government is committed to ongoing monitoring of the clinical effectiveness and cost-effectiveness of medicines after they have been listed on the PBS.

10.2.1 Ministerial approval for a post-market review

A full post-market review will only proceed following Ministerial approval.

Post-market reviews may be initiated at any time, but the main drivers are recommendations by the PBAC or issues identified through the routine monitoring processes of DUSC. Routine monitoring by DUSC occurs at 24 months after the initial listing of a medicine or major changes to the existing listings of a medicine on the PBS.

Post-market reviews may be initiated because of concerns related to the quality use of a medicine, cost-effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences. The department will seek advice from the PBAC and its subcommittees about the scope and potential sources of evidence and input for each post-market review.

10.2.2 Post-market review processes

Post-market reviews are conducted in accordance with a [consultative framework](#) that was agreed to by the pharmaceutical industry representative body (Medicines Australia) and the department.

10.3 PBAC requested research report

The PBAC may request a targeted research on one or more aspects of a PBS-listed medicine or class of medicines.

These targeted research reports are conducted in a collaborative and consultative manner, following similar processes to post-market reviews. They usually have a narrow or single focus such as examination of a medicine's utilisation, clinical effectiveness following release of new evidence, or determining the cost-effectiveness of a listed medicine in a specific group of people. This research may inform further PBAC decision making and/or inform the need for a broader and more comprehensive post-market review.

Appendix A Information sources and contacts

The following information sources and contact details for areas within the Australian Government Department of Health and Aged Care (the department) that may be useful to applicants preparing submissions to the PBAC, or seeking further information about listing medicines/vaccines on the PBS/NIP.

A.1 Online information

The department maintains a website for the PBS and related information for stakeholders.

The Immunisation Australia website is also maintained for information relating to the NIP.

Through the [PBS website](#), the department provides stakeholders, in Australia and internationally, with a broad range of useful information about the operation of the PBS, including:

- the current online PBS Schedule
- detailed schedules and timelines for the PBAC and other listing process, including for new brands of existing pharmaceutical items, and delisting and price increase processes
- information for prescribers and dispensers of medicines under the PBS, and the pharmaceutical industry
- publicly accessible information on the PBAC deliberations (Outcomes and PSDs)
- DUSC outcomes and reports
- access to regular news updates
- access to usage information (PBS and Department of Veterans' Affairs scheme statistics) for research and studies
- current and historical versions of all PBS Schedule documents

A.2 Departmental contact details

A.2.1 PBAC, ESC and submission-related matters

Contact for all general correspondence pertaining to the PBAC:

PBAC Secretariat
 Office of Health Technology Assessment MDP910
 Department of Health and Aged Care
 GPO Box 9848
 Canberra ACT 2601
 Email PBAC: pbac@health.gov.au

Email PBAC Secretariat: pbac@health.gov.au for matters related to:

- the PBAC Guidelines: *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee*
- alternative method to lodging a submission via the HPP
- additional TGA documents during the evaluation period for submissions to the PBAC

- listing documents associated with submissions considered by the PBAC to list on the PBS
- commenting on PBAC Outcomes and PSDs

A.2.2 Matters related to pre-submission meetings and post-PBAC meetings with the Chair

Contact for all matters related to PBAC pre-submission meetings (refer to Section 4.5):

PBAC Pre-submission Meetings
Technology Assessment and Access Division MDP910
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601
Email: PBACpresubmissionmeetings@health.gov.au

Contact for all matters related to post-PBAC meetings with the Chair (refer to Section 7.1.5):

PBAC Secretariat Compliance
Office of Health Technology Assessment MDP910
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601
Email: pbac@health.gov.au

A.2.3 Matters relating to PBS Cost Recovery

Contact for matters relating to cost recovery (refer to Section 4.4):

PBS Cost Recovery Unit
Technology Assessment and Access Division MDP914
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601
Email: pbscostrecovery@health.gov.au

A.2.4 Consumer comments on the PBAC Agenda

PBAC Secretariat
Office of Health Technology Assessment MDP910
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601
Email commentsPBAC@health.gov.au

A.2.5 Matters relating to confirming the price and other post-PBAC recommendation matters

Contact PBS Pricing for all matters about negotiation of the price of medicinal products post-PBAC consideration and other pricing inquiries for medicines listed on the PBS, RSAs and price disclosure operations. This includes information about and lodgement of the Application Form for Pricing Services after the PBAC recommendation. Contact PBS Approvals for any outstanding or amended listing documentation.

PBS pricing: pbspricing@health.gov.au

Price disclosure: pricedisclosure@health.gov.au or (02) 6289 2303

Price Disclosure Data Administrator (PDDA) contact details are available in the [Price Disclosure Guidelines](#). Questions about price disclosure data collection should be directed to the PDDA.

Listing Documentation: pbs.approvals@health.gov.au

A.2.6 Matters relating to estimates of utilisation and financial impact

Email Estimates Section: pbsestimates@health.gov.au

A.2.7 Matters relating to establishment of a Deed

Email PBS Deeds team: pbspricing@health.gov.au

A.2.8 Matters relating to documents for lodgement of new brand of existing pharmaceutical item submissions not requiring PBAC advice, responsible person, guarantee of supply notices, and supply issues for existing PBS brands

Contact for submissions and supporting documents for new brands of existing pharmaceutical items not requiring PBAC advice, responsible person or authorised representative changes for existing PBS brands. For all notifications regarding supply issues contact PBS Pricing:

Email PBS Listing: pbslisting@health.gov.au

Supply issues: pbspricing@health.gov.au

A.2.9 PBS Statistics

Contact for all inquiries about how to obtain use and cost information, prescriptions dispensed, government cost, access to PBS sample data and other data issues:

Email PBS Statistics: pbsstats@health.gov.au

Information on prescriptions and costs is also available through the [Medicare Australia website](#).

A.2.10 Economics Sub-Committee (ESC) Secretariat

Contact for matters considered by the Economics Sub-Committee:

Email ESC: esc@health.gov.au

A.2.11 Drug Utilisation Sub-Committee (DUSC) Secretariat

Contact for matters considered by the Drug Utilisation Sub-Committee including responses to reports prepared by DUSC (Section 9):

Email DUSC: dusc@health.gov.au

A2.12 ATAGI and the National Immunisation Program

ATAGI Secretariat
Department of Health and Aged Care
Immunisation Branch
GPO Box 9848 MDP 13
Canberra ACT 2601
Email: ATAGI.secretariat@health.gov.au

A2.13 HTA Access Point

For applicants requiring information on preparing integrated codependent submissions:

Department of Health and Aged Care

HTA Access Point (HTAAP)

GPO Box 9848 MDP 854

Canberra ACT 2601

Phone: (02) 6289 7550

Email: hta@health.gov.au

Website: [Australian Government Department of Health and Aged Care HTA website](#)

Appendix B – Supporting guidance for PSDs

Supporting guidance for requesting a redaction to specific unpublished clinical data or including a disclaimer in a Public Summary Document

The Department of Health and Aged Care (the department), on behalf of the Pharmaceutical Benefits Advisory Committee (PBAC), has adopted a standardised approach to requests for redacting clinical data in the Public Summary Documents (PSDs) produced for submissions considered by the PBAC. The standardised approach to redaction processes supports the PBAC's commitment for greater transparency and consistency of information published in the PSD.

The approach has three elements:

- **Process simplicity:** Applicants have one (single) opportunity to request redactions of information included in a PSD, prior to its publication.
- **Redaction clarity:** Publication of revised standard ranges for presenting economic and financial information; and publication of all clinical evidence relied upon by the PBAC to inform its decision-making process unless a redaction exception is applied based on one or more of three criteria.
- **Disclaimer requests:** Applicants may request that a disclaimer be included as a footnote to specific data provided specifically for the purposes of PBAC consideration, but which does not meet the criteria for a redaction request.

These elements are outlined in the 7.4 [Procedure Guidance for listing a medicine on the PBS](#).

This supporting guidance document provides applicants with additional guidance on how to appropriately request redaction of clinical data or inclusion of a disclaimer footnote, and information on the level of evidence required to support such requests. It does this by providing examples of 'appropriate' and 'inappropriate' requests.

This guidance document is tailored to requests relating to clinical data. This includes clinical data that are not already in the public domain from any type of clinical study, and from any type of analysis within or across or derived from these clinical studies, and any alternative estimates from sources other than clinical studies. It includes data from demographic measures as well as from outcome measures.

As outlined in the Procedure Guidance for listing a medicine on the PBS, the PBAC's preference is for all clinical data to be published. However, the department will consider redaction requests to clinical data under the three (3) criteria, which are outlined further below.

Criteria for redaction requests:

If no results at all from a clinical study have been published

This criterion pertains to a request for redaction of unpublished clinical data from a clinical study for which *no results at all will have entered the public domain at the time* of publishing the PSD. The applicant must demonstrate that the publication of the information in the PSD will prevent the publication of any results from this study elsewhere, and also that there is a documented

requirement external to the applicant that these results (with or without other results) of the clinical study are to be published once generated.

- This criterion applies to primary analysis of data directly collected from participants recruited into the identified clinical study, such as a randomised trial or a single-arm study.
- This criterion does not relate to secondary analyses across clinical studies, such as from an indirect comparison or a meta-analysis unless it can also be shown that no results from any of the clinical studies included in this secondary analysis would have entered the public domain at the time of publishing the PSD.
- This criterion does not apply in the more common circumstance of where some/any results of a clinical study have already entered the public domain (for which, see next criterion).
- This criterion can apply if the protocol of the identified clinical study has been published (for example, through ClinicalTrials.gov), so long as no results from the study have entered the public domain.

Appropriate redaction request:

The request provides evidence that the release of the specified clinical data in a PSD would prevent publication of any results from the study. It identifies the source (usually the chief investigator) of the clinical study external to the applicant. This source also provides its publication plan relating to its proposed oral or poster presentations as well as manuscript submissions to academic journals, and thus an affirmation from that source that no results from the identified clinical study will have entered the public domain by the time the PSD is scheduled to be published.

If this publication plan also identifies the journal in which the primary publication is intended, and the redaction request is agreed to, then the PSD will identify this proposed journal at the place(s) where the redaction occurs. This is to help the interested reader to find the redacted information in the future.

Where significant portions of data are requested for redaction under this criterion, the applicant also provides a descriptive paragraph, in lieu of the redacted data, to give context for the reader at the place(s) where the redaction occurs.

Where such data are redacted, the department will finalise the descriptive paragraph to ensure the reader can understand the context.

Inappropriate redaction requests:

The request acknowledges that preliminary results of this clinical study have been presented at a conference. However, the primary paper has not yet been published in a journal.

The request states that some data from this clinical study are available on the FDA website. However, the primary paper has not yet been published in a journal.

The request states that the subgroup analysis was specifically derived from the published clinical study for the Australian PBAC submission and this analysis has not been published.

These three requests do not meet the essential prerequisite of this criterion; specifically that no results at all have been published from the identified clinical study. Note that, in these instances,

the disclaimer described in 7.4.6 [Procedure Guidance for listing a medicine on the PBS](#) can be applied.

The request is for redaction of results of comparisons across clinical studies because the specified comparative data have not been published.

The request states that no results of the indirect comparison are in the public domain and disclosing the specified data may jeopardise its future publication.

The request states that the existence of the meta-analysis is not in the public domain and disclosing the specified data may jeopardise its future publication.

These three requests require additional justification. The applicant needs to demonstrate that no results from any and all of the clinical studies included in the indirect comparison or meta-analysis have been published, and publication of the material in the PSD would prevent the future publication of any results from any of these clinical studies. Note that, in these instances, the disclaimer described in 7.4.6 [Procedure Guidance for listing a medicine on the PBS](#) can be applied.

If the unpublished data have been submitted for publication in an identified journal

This criterion pertains to a request for redaction of clinical data that are included in a draft manuscript that has been submitted for publication in an identified journal. The applicant must demonstrate that the publication of the information in the PSD would prevent publication in that journal.

- This criterion only applies where the applicant has already submitted for journal publication and can provide all of the following evidence to support redaction under this criterion:
 1. Evidence of receipt of the submitted manuscript by the identified journal
 2. A copy of the submitted manuscript clearly identifying the clinical data requested to be redacted in the PSD
 3. Evidence that the publication of data in the PSD would prevent publication in that particular journal. Such evidence may include providing the prospective journal's specific rules concerning pre-publication of data.
- This criterion does not apply where an applicant indicates that it intends to submit for journal publication at some stage in the future.

Appropriate redaction request:

The request provides evidence that release of the specified data would prevent the publication of that data in an identified draft manuscript submitted to a specified journal. The supporting information identifies the journal in which the manuscript has been submitted for publication, provides evidence of receipt of the submitted manuscript by that journal, provides a copy of the submitted manuscript with clinical data requested to be redacted clearly identified (for example by highlighting the relevant clinical data or providing annotations using comment boxes in the document), and provides that journal's specific rules preventing publication in the context of pre-published data.

If the redaction request is agreed to, then the PSD will identify this journal at the place(s) where the redaction occurs. This is to help the interested reader to find the redacted information in the

future. The manuscript submitted to the Department will be kept confidential and will only be referred to for the purposes of confirming the specific redaction requests.

The International Committee of Medical Journal Editors (ICMJE) does not consider the reporting of scientific information about a drug by a government agency to jeopardize publication plans. However, this reporting should be discussed with and agreed upon by the editor in advance where possible.

Where significant portions of data are requested for redaction under this criterion, the applicant also provides a descriptive paragraph, in lieu of the redacted data, to give context for the reader at the place(s) where the redaction occurs.

Where such data are redacted, the department will finalise the descriptive paragraph to ensure the reader can understand the context.

Inappropriate redaction request:

The request advises that the investigators intend to send the specified data to a journal for publication.

The request indicates that Global has advised the specified data are included in a publication plan.

The request advises that Global is unable to provide the required evidence to support a redaction request under this criterion before the publication of the PSD.

These requests require additional justification. The applicant needs to demonstrate that publication of the material in the PSD would prevent the publication in an identified journal. The evidence required to support this request includes evidence of receipt of the submitted article by the journal, a copy of the submitted manuscript in which the clinical data requested to be redacted in the PSD is clearly identified, and evidence that the publication of data in the PSD would prevent publication in that particular journal. This evidence should be anticipated prior to lodging a submission to PBAC. Requests that indicate that more time is required to provide the evidence will not be accepted. Note Criterion 1 may be applicable for these examples if no results at all will have entered the public domain at the time of publishing the PSD.

If the unpublished data will breach clinical study participant confidentiality

This circumstance pertains to a request for redaction of clinical data that can be shown to potentially breach clinical study participant confidentiality.

- As the clinical data relied upon by PBAC is routinely presented as summary data, and not even de-identified individual patient data, this basis for a request for redaction has not occurred to date, and is considered extremely unlikely to occur in the future. Nevertheless, given the ethical principle of personal privacy involved, it is an important option to identify.

Appropriate redaction request:

The request relates to the results of a sub-group analysis involving extremely low patient numbers, where cross-referencing with other information from that study and or elsewhere in the public domain is likely to enable re-identification of one or more particular study participants. The

request also demonstrates how this re-identification of study participants is possible from the specified information sources.

Where significant portions of data are requested for redaction under this criterion, the applicant also provides a descriptive paragraph, in lieu of the redacted data, to give context for the reader at the place(s) where the redaction occurs.

Where such data are redacted, the department will finalise the descriptive paragraph to ensure the reader can understand the context.

Inappropriate redaction request:

The request is to redact the numbers of patients in each arm of a study.

The request is to redact the numbers of patients in each subgroup of a study.

Neither of these requests would allow re-identification of an individual study participant.

Basis for disclaimer requests:

Where specific clinical data have been provided specifically for the purposes of PBAC consideration, but it does not meet the criteria for a redaction request, the applicant may instead request that a disclaimer be included as a footnote to that specific data in the PSD to further inform the reader.

Appropriate footnote request:

The request provides evidence that the specified clinical data were generated by the applicant beyond the pre-specified statistical plan for the clinical study, or identifies where the specified analyses were first presented in the commentary, ESC Advice or PBAC Minutes.

The applicant affirms that, to the best of its knowledge at the time of making its request, the clinical data were only provided for the purposes of informing the PBAC consideration.

Inappropriate footnote request:

The identified clinical data were generated in accordance with the pre-specified statistical plan for the clinical study, or have been submitted elsewhere.