Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme

(including consideration of vaccines for the National Immunisation Program)

Version 1.0

October 2016

Australian Government
Department of Health
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Shortened forms and definitions

Acronyms and abbreviations

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Definitions

Sponsor

The sponsor of a submission seeking listing on the PBS. ‘Sponsor’ is used interchangeably for the following – a pharmaceutical company sponsoring the TGA application or marketing the product in Australia, and an organisation or individual supporting the preparation of a submission. Sponsors are also referred to as responsible persons in the National Health Act 1953 and Regulations in relation to price agreements and listed products.

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 which is 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.
1 Purpose

This guide describes the processes undertaken by the Department of Health 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.

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 document called Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee (the PBAC Guidelines) to provide organisations preparing submissions to the PBAC with the information required by the PBAC. The PBAC Guidelines should be consulted by any organisation seeking to list a medicine or medicinal product on the PBS or a vaccine on the NIP. However, those 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 procedure guidance is an accompanying document to the PBAC Guidelines. This document explains the processes that the department has put in place to:

- provide support for organisations seeking to prepare submissions
- provide information on the types and structure of submissions and additional documents required
- provide an explanation of evaluation procedures for medicines and vaccines and management of materials
- list the procedures that the Government requires to list a medicine or medicinal product on the PBS
- explain how the products on the PBS are reviewed once listing on the PBS is completed.

This document is maintained by the department. The document is routinely revised in response to changes to the processes involved in consideration and listing of medicines on the PBS and vaccines on the NIP.

Any comments or questions of a general nature about the topics included in the guidance, accuracy of the content or other matters should be forwarded to the department (refer to Appendix A).
# Listing process

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

Figure 2.1  Timeline of PBAC procedures
3 Confidentiality and transparency

The Australian Government, and the PBAC and its subcommittees, are conscious of the need to be as open as possible in proceedings and 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 as a consequence of the 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 sponsors to list medicines/vaccines on the PBS/NIP, other general submissions to the PBAC, all agenda items considered by the PBAC, and other letters and applications made directly to the Australian Government Department of Health. 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 of Health’s website about the AUSFTA.

3.1 Managing and assessing confidential material

3.1.1 Material contained in submissions

**Australian Government Department of Health**

Electronic and paper-based records are maintained by the Australian Government Department of Health 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 usually supplied in electronic format (refer to Section 5). The USB or a similar storage device that is supplied by sponsors is kept in a secure storage area in the Pharmaceutical Benefits Division (PBD), and access to the area is limited. Submissions that are emailed are stored in the Department of Health’s IT system. General submissions and other correspondence are filed and stored in a secure area within the Pharmaceutical Evaluation Branch (PEB) and electronic copies are made for the PBAC agenda. The contents of all submissions are stored in the Department of Health IT system in the electronic format that was provided in the submission.

Access to the contents of the submission is limited to officers who need to work on the submission material. Access is controlled by senior officers in PEB.

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

**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.

Signed deeds of confidentiality are required by all people undertaking evaluations or other work for the PBAC. 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 in regard to 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 Office of Health Protection, 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 Department of Human Services.

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. PEB 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 interests 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 conflict of interest with submissions to be considered. Each group informs 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 Subcommittee (DUSC) releases outcome statements and reports about the use of medicines that are currently listed on the PBS.

In addition, public release of documents about the proceedings of the PBAC forms part of the Australian Government’s commitment to transparency under the AUSFTA.

Currently, three sets of documents associated with the PBAC consideration of medicines are publicly released. In addition, there are two sets of information about medicine utilisation released by DUSC.
3.3.1 PBAC Agenda

A list of submissions that will be considered by the PBAC is published on the PBS website 10 weeks before the date of the PBAC meeting. 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

Decisions of the PBAC, PBAC Outcomes, excluding determinations related to price only, have been reported publicly since June 2003.

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). The publication of PSDs provides information on the evidentiary basis for PBAC recommendations and the rationale for these recommendations.

Most PSDs are published 16–18 weeks after the PBAC meeting (see Section 7.4).

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 sponsors – 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.
4 Presubmission requirements

The Australian Government Department of Health provides a range of documents and services to assist sponsors and other organisations who wish to prepare and submit a submission to the PBAC for:

- listing a new medicine on the PBS or 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 sponsors 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 4.1 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. Submissions generally need to be lodged by 4 pm on the specified days. Sponsors who need to lodge later than 4 pm should notify the department ahead of time (refer to contact details in Appendix A).

4.1 Types of submissions

There are four different types of submissions for listing medicines on the PBS and vaccines on the NIP. These are described in general terms below.

The *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* (see Section 4.4) set out rules for categorising submissions. The descriptions below should only be considered as a general guide and in relation to cost recovery matters this guide does not take precedence over the Cost Recovery Regulations.

Sponsors who are uncertain of the type of submission required should contact the department with a request for further information (refer to contact details in Appendix A). Where a submission has been made and is considered by the department to be misclassified, the department will review and reclassify the submission.

All submissions to the PBAC must adhere to the structure and information requirements set out in the *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee*. However, not all submissions will require information in response to all parts of the PBAC Guidelines (e.g. minor and minor committee secretariat submissions). Most requests for listing a new brand of existing pharmaceutical item do not require consideration by the PBAC.

Major submissions are required to be submitted 17 weeks before the PBAC meets.

Minor submissions (including committee secretariat submissions) are required to be submitted 11 weeks before the PBAC meets.
Submissions for a new brand of an existing pharmaceutical item that do not need to be considered by the PBAC are forwarded directly to the department (see Section 4.1.4 for details).

4.1.1 Major submission

Major submissions generally relate to requests for the listing of a new medicine or vaccine, a new indication for a currently listed medicine, or to make material changes to a currently listed indication where an economic model is required to support a claim of cost-effectiveness, cost-utility or cost-minimisation.

A resubmission is classified as a major submission where a new or updated economic model is necessary to support the claims made in the submission, or if there are other changes to the submission that require evaluation.

In unusual cases a major submission may be required for a new form or strength of an already-listed medicine that is not bioequivalent to an existing listed form of the medicine. This may be necessary to demonstrate that the new form delivers similar clinical outcomes to the existing form.

Major submissions may also include submissions requiring a codependent technology to be listed on the Medicare Benefits Schedule (these are also referred to as integrated codependent technology submissions).

4.1.2 Minor submission

Minor submissions generally relate to requests to change existing listings that do not change the population or cost-effectiveness of the treatment, or the listing of a new form or strength of an already-listed medicine that has a bioequivalence or equivalence statement from the TGA. An economic model (or revised model) is not necessary to support the claims made in the submission.

As PBAC advice is required on a case by case basis regarding the potential for schedule equivalence for biosimilar listings, minor 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 minor submission process in some other circumstances (e.g. some resubmissions and some new brands of existing pharmaceutical items with an unusual presentation, potential equivalence, substitution or quality use of medicines issues).

4.1.3 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.

4.1.4 New brand of an existing pharmaceutical item

This submission type is for listing an additional brand (a generic medicine) of an existing TGA-approved and PBS-listed pharmaceutical item where there is no requirement for consideration by the PBAC as a minor submission. (See section 4.1.2 for those requiring a minor submission). Evidence of equivalence from the TGA must be provided.
4.1.5 General correspondence to the PBAC

Individuals, organisations and other consumers may raise issues for consideration by the PBAC. These may not have evidence for evaluation. 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 major submissions in the Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee. The PBAC Guidelines contain specified information requirements for fixed-dose combination products, nutritional products, vaccine products and codependent technologies.

Guidance for preparation of minor submissions uses elements of the PBAC Guidelines for major submissions. The structure of a minor submission should include appropriate or applicable elements of Sections 1 and 2 of the PBAC Guidelines. In addition, if there is any financial impact for the government, the sponsor needs to complete the applicable section of the Section 4 Workbook (Excel format) and provide this in the submitted documents.

4.3 Timeframes for the PBS

4.3.1 Key dates for PBAC and subcommittee meetings, submission lodging

A calendar of 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.

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.

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, which is published monthly. This includes lodging deadlines for new brands of existing pharmaceutical items, and other PBS deadlines (e.g. delisting and price increase requests).

4.4 Cost recovery

From 1 January 2010, amendments to the National Health Act 1953 provide authority for the cost recovery of Australian Government–funded services from sponsors 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 2009 (Cost Recovery Regulations).

Cost recovery provides an important means of improving the efficiency with which Australian Government products and services are produced and consumed. The cost of evaluating, pricing and listing medicines, vaccines and other products or services on the PBS or the NIP was previously fully funded by the taxpayer. Fee revenue is returned to Australian Government consolidated revenue.
and remains separate to the consideration of submissions by the PBAC and the listing process on the PBS or the NIP.

The procedures for cost recovery are undertaken by the department and the sponsor. The PBAC, other committees and groups involved in the evaluation or listing processes are not informed or aware of cost-recovery decisions. The cost-recovery process has no effect on the evaluation of the submissions.

### 4.4.1 Fees for cost recovery

A [PBS service fee application form: to accompany PBAC submission](#) will need to be completed for any major or minor submission to be considered by the PBAC.

The completed application form must be lodged at the same time as the submission. The form requires a ‘self-assessment’ by the sponsor as to the evaluation category of the submission to the PBAC – that is, whether it is a major or minor submission for the purposes of cost recovery. Additional information can be found in Section 4.1 of the Cost Recovery Regulations on the [PBS website](#) or by emailing the PEB (refer to Appendix A).

When the department receives the submission and the application form, the fee category self-assessment (as indicated by the sponsor) is checked against the Cost Recovery Regulations. After the assessment, an invoice and request for payment letter is emailed to the sponsor. Cost-recovery fees are payable within 28 days of notification.

In certain circumstances, an exemption or waiver of fees may apply, detailed in Part 5.1 of the Cost Recovery Regulations. Examples of fee exemptions include submissions identified by the TGA as an ‘orphan drug’ or where a medicine is for ‘temporary supply’.

The sponsor must supply supporting documentation with the application form at the time of lodgment. A sponsor may apply to the Secretary of the Department of Health to waive the fee if the submission involves a public interest and where payment of the fee would make the application financially unviable. Further details may be found in Part 5.2 of the Regulations. The Secretary (or delegate) of the Department of Health may request further information from the sponsor and/or other sources before making a decision.

A sponsor may withdraw a submission any time after lodgment. Where a sponsor withdraws the submission, the sponsor must provide written notice of withdrawal to the department (refer to Appendix A for contact details) within 14 days of receiving the invoice. The request must be in writing, on appropriate company letterhead, and signed by a suitably authorised representative of the sponsor before being emailed or posted to the department (refer to contact details in Appendix A).

After withdrawing a submission, if the sponsor:

- provides evidence of withdrawal within 14 days of receiving the invoice, there will be no charge and the invoice, if raised, will be cancelled
- has already paid the invoice, there will be a full refund of any fees paid
- does not provide evidence of the withdrawal of a submission within 14 days, the sponsor will be liable for the cost-recovery fee, because the costs associated with evaluation of the submission have started.

Sponsors should note that the requirement to provide an email to the PBS Cost Recovery officers is in addition to any communication with PEB officers managing the agenda for the upcoming PBAC
meetings regarding withdrawing the submission from consideration (refer to Appendix A for contact details).

4.4.2 Submission categories for cost-recovery fees

The submission categories for the purpose of cost recovery, and associated fees, are defined in the Cost Recovery Regulations (see also Section 4.1 for descriptions of the submission types). The Regulations also provide for an independent review (see Section 7.2 for details).

4.4.3 Fee payment

The Cost Recovery Regulations underpin PBS and NIP cost recovery.

Part 4.7 of the Regulations provides for the annual indexation of fees based on increases in the Consumer Price Index (CPI). As per the Australian Government Cost Recovery Guidelines, a periodic review of all existing and potential charging activities must be conducted at least every 5 years. Information on the current indexed fees can be found on the PBS website.

Any queries about an invoice raised should be emailed to PBS Cost Recovery (refer to contact details in Appendix A).

Fees are to be paid within 28 days of notification. The invoice is sent to the responsible person nominated by the sponsor by email. Payment should not be forwarded before receiving an invoice from the department. In some circumstances, where short timeframes are required before the department incurs major expenses – for example, if undertaking an independent review – a 14-day terms of trade for payment will be required.

Three payment points have been identified:

- when lodging a submission, including resubmissions (see Section 5)
- at the completion of pricing negotiations (see Section 8.1)
- at the request for an independent review of a PBAC decision (see Section 7.2).

Payment should be made by electronic funds transfer (EFT) to the account nominated on the invoice. The invoice number must be entered in the free-text portion of the EFT transaction when paying. A request for payment letter, which will accompany the invoice, will advise the sponsor of a unique identifying number assigned by PEB to identify the application for payment of fees through the fee process.

Fees must be paid in full at the time of payment. Payment by instalment will not be accepted unless previously arranged with the department’s delegate.

If a pharmaceutical company or other organisation has a computerised financial control system and needs to add the Department of Health to the system for processing payments, contact the department to advise of the issue and provide a copy of the form used by the company detailing the information required (refer to contact details in Appendix A).

If an invoice is not paid within 28 days, the department may stop processing the submission until the fee is paid. Before evaluation work halts, or the invoice is referred for debt-recovery action, the department will contact the sponsor.

Unpaid fees shall be a debt owing to the Australian Government and will be subject to standard Australian Government debt-recovery actions.
4.4.4 Disagreement or dispute procedures

Should the sponsor disagree with the delegate’s fee determination, the Cost Recovery Regulations provide for a review process. Further details on rights of review can be found in Part 6 of the Regulations.

Where a sponsor disputes the decision on the cost-recovery fee, the sponsor must forward a request for a review, in writing, to the department within 14 days of receiving the invoice (refer to Appendix A for contact details).

4.5 Presubmission meetings

The department can provide presubmission advice on the preparation of major submissions to the PBAC to list a medicine on the PBS or vaccine on the NIP. This advice is not binding on the PBAC.

Examples of issues that benefit from a face-to-face presubmission meeting are where:

- the medicine or vaccine is the first of a class in a therapeutic area, and in particular where a cost-effectiveness claim is being made
- the medicine or vaccine is an extension of indication for a currently listed restriction and there will be a cost-effectiveness claim in the submission
- the outstanding issues raised in a resubmission require a substantial rewrite 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
- the sponsor 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 (eg 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 department also meets with representatives of pharmaceutical companies to discuss regulatory and subsidy issues for newly emerging classes of medicines, while these products are being developed by the pharmaceutical company, to provide advice on trial design. Depending on the matters for discussion, attendance at these meetings can include officers from the TGA, PBD and MBD.

4.5.1 Arranging a presubmission meeting

A sponsor can email a request for a presubmission meeting to the department (refer to Appendix A for contact details). The relevant departmental officers will forward a response, including a request for information, that will help the department to allocate the correct time and ensure appropriate staff are consulted before the meeting.

The department allocates times in specific weeks for presubmission meetings. These are available on the PBS website. One or two medicines/vaccines can be discussed at each meeting. For two medicines, up to 1.5 hours will be allocated. If the sponsor wishes to discuss more than two medicines/vaccines, an additional meeting is required. Where a sponsor proposes to discuss a vaccine submission, the PBAC Secretariat will contact the relevant departmental officers in the ATAGI Secretariat in the Office of Health Protection. A representative from the ATAGI Secretariat may attend the meeting, if appropriate.
Meetings for medicines or vaccines that are considered integrated codependent submissions are held during the same allocated weeks and arranged in consultation with any other relevant area (eg the Medical Services Advisory Committee [MSAC] Secretariat). Sponsors should contact the Health Technology Assessment Access Point (HTAAP) if they have an integrated codependent submission (refer to Appendix A for contact details).

The agenda for the presubmission meeting and any relevant papers need to be provided to the department at least 14 calendar days before the meeting (refer to Appendix A for contact details). If this is not done, the department may not be able to adequately prepare for the meeting or ensure that all relevant officers are present. In the event that the agenda papers are not provided by 14 calendar days before the presubmission meeting, the department may cancel or reschedule the meeting.

Agenda papers are reviewed by the department before the meeting. If the briefing documents are unclear about the issues on which advice is sought, the department may contact the sponsor for further information. The department and sponsor representatives can discuss the need for having a meeting if issues remain unclear and the benefit of seeking advice from the department is doubtful.

The agenda papers should include a briefing document that contains an overview of the approach intended for the submission and any specific issues on which the department’s advice is sought. The documents should be concise and highlight the specific areas that the sponsor is seeking advice about (eg appropriate comparator, applicability of the studies, economic model, utilisation, developing a risk-sharing approach in the submission). Where sponsors are specific in their requests, the department can seek advice from all relevant areas and provide useful advice to the sponsor.

The department does not accept bookings to discuss submissions within 14 calendar days of the proposed date of lodgment of the submission.

**4.5.2 Department of Health attendees**

The officers in the Health Technology Assessment (HTA) area are responsible for reviewing the agenda papers and determining which staff from the department should attend, to make the meeting as useful to the sponsor as possible. This may include officers from HTA, drug utilisation and estimates, and pricing.

Departmental program areas that may be involved in evaluation or listing of the medicine or vaccine will also be invited to the presubmission meeting where required. For example, if a vaccine is under consideration, officers from the ATAGI Secretariat may be invited to attend.

Members of the PBAC and its subcommittees do not attend presubmission meetings.

**4.5.3 Sponsor attendees**

The sponsor should advise the department who will be attending the presubmission meeting and what their role at the meeting will be.

The sponsor is able to bring employees of their organisation, and members of professions such as health professionals or other health service providers. The sponsor should advise the department if attendees are contractors assisting in preparation of the submission and the name of the contracted organisation.

As the purpose of presubmission meetings is to provide technical advice, PBD holds presubmission meetings with the expectation that any external contractor will be present at the presubmission
meeting in a technical role and not in any capacity as a lobbyist. The department does not support the use of presubmission meetings for the purpose of 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 on the Australian Government Department of the Prime Minister and Cabinet website.

4.5.4 Conduct of the presubmission meetings

Meetings will be 1–1.5 hours long, depending on whether advice on submissions for one or two medicines or vaccines is sought.

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

The department does not prepare meeting minutes, and does not review or agree to any meeting notes or outcomes written up by the sponsor about the meeting discussions.

Attendees may teleconference into the meeting. While the department is aware of the time differences between Europe, the Americas and Australia, it is generally not possible to change the meeting times to accommodate people who want to attend through teleconference.

The presubmission meetings are intended to provide sponsors with departmental advice based on its understanding of the PBAC Guidelines and relevant previous decisions made by the PBAC. They are also meant to identify any other system issues that may arise in consideration of the submission by the PBAC. Sponsors must form their own judgments about if and how to use departmental advice, and advice from the department is in no way binding.

4.6 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.

Sponsors 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 PBD if required. Further details are available on the department’s HTA webpage. Contact details for the HTAAP are in Appendix A.
5 Lodging submissions for listing medicines or vaccines

All submissions are to be indexed, paginated and written in English, and with all currency in Australian dollars. All parts of all types of submissions should be clearly labelled and information in the submission located easily by readers.

5.1 Lodging a submission

All major and minor submissions with a file size greater than 30 MB are supplied on a USB storage device and posted to the PEB. If necessary, these storage devices can be delivered to the offices of the PEB, Department of Health in Canberra. Contact departmental officers in the Submissions Lodgement Area via email to arrange for them to receive the submission.

Minor submissions with a file size of less than 30 MB can be lodged with the Submission Lodgement Area via email.

New brand submissions are emailed to the department.

Correspondence should also be submitted electronically where possible. Letters sent to the PBAC Secretariat may be accepted by post.

Department officers acknowledge and review submissions after lodgment.

See Appendix A for contact details

5.2 Submission formats

All major submissions are only accepted in electronic format. Supply the whole submission, including all appendixes and attachments, on two clearly labelled USB storage devices. The devices must be fully accessible by departmental personnel, submission evaluators, and members of the PBAC and its subcommittees.

If departmental officers cannot access the information on the USB devices, the sponsor will be notified within 24 hours and the USB devices returned by express post.

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®.

If the sponsor would like to provide submission information in another software format, the sponsor must contact the department before the submission is lodged (refer to Appendix A for contact details). 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 sponsor 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 sponsor that the evaluation of the relevant section of the submission is incomplete, and analyses or models could not be verified independently.

## 5.4 Major submissions

Refer to the document table in the *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee* for a checklist of some required documents for major submissions.

The electronic documents should be lodged in a series of folders labelled:

- **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.

- **TGA documents.** The following documents (where available) should be provided in this folder:
  - TGA clinical evaluator’s report
  - TGA delegate’s overview
  - minutes of the Advisory Committee on Prescription Medicines
  - TGA risk management plan
  - confirmation of registration in the Australian Register of Therapeutic Goods
  - the most recent Product Information
  
  Refer to Section 6.3 for additional information about providing documents where major submissions are being evaluated under TGA parallel processing.

- **Key documents.** The following completed documents are required by the department
  - submission cover letter on company letterhead signed by an authorised company representative. This should include an index list of all documents provided, to help check that all documents are present
  - PB11
  - PB11b, available on the PBS website
  - PBS Service Fee Recovery form
  - restriction template (if applicable)
  - complete and approved Australian Digital Health Agency AMT Mapping form (in Microsoft Word).

  The request for a specific restriction is included in Section 1 of the main body of the submission. Information on how PBS restrictions are created in the current format and a template is available on the ‘Checklists and templates’ page of the PBAC Guidelines website.

- **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 sponsor 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.** Provide any required attachments 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.
  - Section 3 models or cost-minimisation spreadsheets
  - Section 4 financial estimates workbook.

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 (ie 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 (eg 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 Minor submissions

The electronic documents should be provided in a series of folders labelled:

• **Main body of the submission.** Minor submissions generally require relevant information requested in Sections 1, 2 and 4 of the PBAC Guidelines. Minor submissions need to estimate the financial cost to the Australian Government of listing the medicine on the PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS) and vaccine on the NIP or PBS. Therefore, the documents provided as an attachment include the Excel spreadsheet ‘Estimates of patient use and financial cost’. Minor submissions may also need to provide information requests from Section 2 of the PBAC Guidelines. There may also be instances where a minor submission has
additional information to be provided – for example, at the request of the PBAC following its previous consideration of the medicine or vaccine as a major submission.

- **References.** Separate electronic documents for all references used in the submission.
- **Appendixes.** Copies of supporting material for Section 4.
- **Key documents.** The following completed documents are required by the department
  - Submission cover letter on company letterhead signed by an authorised company representative. This should include an index list of all documents provided to help check that all documents are present
  - PB11
  - PB11b
  - PBS Service Fee Recovery form.

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

- restriction template
- 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 5.7 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 minor submissions.

### 5.7 New brand of existing pharmaceutical item submissions (not requiring PBAC consideration)

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

The departmental delegate considers a submission to list a new brand of an existing pharmaceutical item. Information in the submission is required to assist when considering making a price agreement and listing the brand, and potentially for determining an originator brand under s99ADB of the *National Health Act 1953*.

The delegate considers an originator brand determination when listing a new brand of a medicine on the F2 formulary (including biologics). The initial originator brand determination for a drug generally occurs at the same time as the drug moves to the F2 formulary. New brand name variants of existing originator brands are also intended to be originator brands (see the *National Health Amendment (Pharmaceutical Benefits) Bill 2015 Explanatory Memorandum*). On occasion, other new listings for an existing F2 drug may also be considered by the delegate for originator determination – for example, a different new formulation or a new manner of administration. Further information
about originator brand determination is available in the Fact Sheet about 2015 Price Disclosure changes. The current originator brand legislative instrument is called the National Health (Originator Brand) Determination and can be located on the Federal Register of Legislation.

Submissions for a new brand 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 and currently listed brands. In some instances the new brand may not have TGA approval for all indications of the currently listed brands. In this event, the new brand will only be listed for the approved indications.

Include the following documentation in a submission for a new brand:

- a submission cover letter on company letterhead signed by the responsible persons authorised representative. The cover letter must include a signed supply assurance 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 dispensers) in time for the PBS listing day, and a hyperlink to the TGA-approved Product Information
- a TGA bioequivalence statement
- any comments on potential determination of a new listing brand as an originator brand
- a completed and signed Responsible Person form, which includes the authorised representative
- a PB11a form should be provided to PEB by the final documentation deadline (refer to Section 8.1).

The contact details for lodging submissions for new brands of existing pharmaceutical items that do not require PBAC advice are provided at Appendix A2.9.

5.8 Providing documents after lodging a submission

For submissions where the TGA delegate’s overview is provided with the submission documents, additional regulatory documents may be updated while the submission is being considered by the PBAC. Sponsors 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 (medicines only), the 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 Prescription 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 major submissions is under way. However, if the sponsor becomes aware of new publications or further data analyses that have relevance to consideration of the submission by the PBAC, the sponsor 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 (ie 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 PBAC membership is prescribed in the *National Health Act 1953*. 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 sponsor 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 Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee.

Selection of submissions and reports for consideration

ESC considers all major 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 the PBAC as a document called the ESC Advice. This is also provided to the sponsor. An ESC Advice is prepared for each major submission and report considered by ESC.

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 evaluates use and financial forecasts of selected major submissions to the PBAC.

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

Selection of submissions and reports for consideration

DUSC 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.

DUSC reviews the PBS listing for medicines that have been listed for an initial period of 24 months. The subcommittee selects individual medicines or groups of medicines to be reviewed (refer to Section 9.1). The sponsor is informed of the review after the meeting at which the selection of the medicine for review is made. Planned reviews are also listed in the outcomes of the DUSC meeting, which are published on the PBS website.
**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 sponsor.

### 6.2 Evaluation of submissions

All major 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 major 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 PEB.

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 major 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 sponsor. The sponsor 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 the major 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 sponsor with the ESC Advice.

### 6.3 Management of parallel process submissions

Since 1 January 2011, the Australian Government has allowed major submissions to be evaluated at any time from the lodgment of a TGA registration dossier. This policy is called the TGA–PBAC parallel process.
The sponsor 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 5.7).

Where the TGA has not generated a TGA delegate’s overview by one week before the PBAC’s meeting, the PBAC may defer its final decision regarding a recommendation for subsidy or not recommend the medicine.

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

The PBAC does not provide information on its consideration of a submission to the public through an outcome statement until the TGA delegate’s overview is prepared. The Public Summary Document is not published until the medicine is registered for that indication by the TGA.

To date, parallel processing of submissions with the TGA has not been extended to minor submissions or vaccine submissions.

6.4 Input of the sponsor 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.

Sponsors 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 major submissions, sponsors 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 minor submissions, sponsors have one opportunity to provide written input for the PBAC. This input is called the pre-PBAC response.

6.4.1 Pre-subcommittee response

Sponsors receive the commentary on a major submission 14 calendar days before the meetings of ESC and DUSC. Sponsors have seven calendar days to prepare and provide a response to the department for inclusion in ESC’s and DUSC’s agenda papers. The response must be provided by midday on 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 major submissions are limited to four pages of text, and two pages of graphs and tables. Where the evaluation is for an integrated codependent major submission, the sponsor 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 sponsor with a major submission 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.

Sponsors 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 (eg vaccines is in Section 6.5).

For minor submissions, sponsors 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 minor submissions and, if this is the case, the DUSC Advice is also given to sponsors.

Sponsors have seven calendar days to prepare and provide a pre-PBAC response to the department to include in the agenda papers of the PBAC. The response must be provided 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, sponsors may provide six pages.

6.4.3 PBAC hearings

A sponsor submitting a major submission can make an oral presentation to the PBAC during the PBAC meeting. The content of these presentations is limited to matters raised in their submission, during the evaluation, or as part of the advice prepared by the subcommittees. No new evidence is to be presented.

6.4.4 Procedures to request a hearing

A sponsor requesting a hearing should contact the department (see Appendix A) at least 12 calendar days before the PBAC meeting. Sponsors 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 sponsor who prepared the submission, the names and affiliations of each person should be supplied at least seven days before the PBAC meeting. Each invited non-employee of the sponsor 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 sponsor 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 NIP and other related issues. It is a nonstatutory committee comprising experts in immunisation, public health, infectious diseases and consumer issues, as well as medical practitioners and nurses.

ATAGI meets face to face three times a year in February, June and October.

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. The terms of reference of ATAGI are available through the Immunise Australia 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.

The ATAGI Secretariat is located in the Department of Health. The secretariats of ATAGI and PBAC liaise regularly to ensure both committees work effectively together to consider submissions to list vaccines on the NIP.

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.

Sponsors preparing a submission for a vaccine can request a presubmission meeting with the department (refer to Section 4.5).

Presubmission advice

PBAC requires presubmission advice from ATAGI for each vaccine submission. ATAGI presubmission advice is prepared by the relevant ATAGI Working Party and endorsed by ATAGI at one of its face-to-face meetings. It is provided to the sponsor soon after endorsement.

Sponsors are required to make a formal request for ATAGI presubmission advice through the ATAGI Secretariat. All requests are required to be lodged at least six months before the ATAGI meeting in which the advice is to be endorsed (refer to Appendix A for contact details).

Sponsors are expected to include the ATAGI presubmission advice as part of the submission to the PBAC to list a vaccine on the NIP.

ATAGI consideration of the content of the submission

Sponsors with questions for ATAGI regarding the ATAGI presubmission advice or the processes for listing vaccines on the NIP should contact the ATAGI Secretariat (refer to contact details in Appendix A).
Response to questions raised during the evaluation (postsubmission advice)

A copy of the submission to list a vaccine on the NIP is provided to the Chair of ATAGI and the Chair of the relevant ATAGI Working Party.

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 ATAGI postsubmission advice. In developing ATAGI postsubmission advice, the relevant ATAGI Working Party will consider the evaluators’ questions alongside the vaccine sponsor’s PBAC submission. During this phase, ATAGI may seek additional information from the sponsor to help respond to the evaluators’ questions.

ATAGI endorses its postsubmission advice at one of its face-to-face meetings. The document is then provided to ESC, the PBAC and the sponsor.

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

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 sponsor and PBAC (refer to Section 6.1.2).

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.

6.5.2 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, the Office of Health Protection will start the necessary steps to amend the National Health (Immunisation Program-Designated Vaccines) Determination (refer to Section 8.7). 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.

NPWP members include individuals with expertise in paediatrics, general practice, dietetics, the pharmaceutical industry and consumer interests. One member of the NPWP is a member of the PBAC.
Sponsors seeking to list a medicinal food on the PBS must provide a minor submission to the PBAC, consistent with the requirements outlined in the *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee* 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

Sponsors receive a copy of the NPWP Advice to the PBAC. The sponsor 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 than 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 10 weeks before the PBAC meeting.

Consumers are invited to make comments (electronic format) that are submitted directly to the department. There are six weeks to make comments. Comments may be made by any organisation or individual. 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 sponsor and the PBAC. The complete summary of comments from groups or organisations will be provided to the PBAC and the sponsor.

#### 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 seeks 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 sponsor if additional information is sought, and from whom. Where the responding organisations or individuals agree to release their information to the sponsor, 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. 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. Stakeholder meetings do not replace presubmission or post-PBAC consideration meetings between the department and the sponsor
- where the committee is aware that sponsors are preparing to submit major 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 may provide the PBAC and stakeholders with a greater understanding of the issues and suggest ways to resolve some of the outstanding matters.

The aim of each meeting is to inform stakeholders of the situation and seek their views. These meetings provide information, and are not a de facto appeals mechanism.

The sponsor 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. The PBAC will consider the request at the earliest opportunity.

Meetings with stakeholders are not 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.
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)
- sponsors 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 21 calendar days of the meeting. Attendees will receive five 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 medicinal and medical service components of an integrated codependent submission are evaluated by the same evaluation group 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.

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

6.11.2 Streamlined codependent submission processes

Where a major submission or major resubmission is lodged for PBAC consideration, lodge the accompanying streamlined submission to MSAC at the same time. Standard PBAC processes apply to the major submission to the PBAC. An overview of the streamlined submission to MSAC is prepared by the department and will be provided to the sponsor according to the standard pre-MSAC process.
7 Post-PBAC decision procedures for sponsors

7.1 Notification of outcomes of PBAC

Table 7.1 shows the timeframe for notification of PBAC outcomes.

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>PBAC outcome provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three weeks after PBAC meeting</td>
<td>Ratified PBAC Minutes for positive recommendations by email (Section 7.1.1)</td>
</tr>
<tr>
<td>Five weeks after PBAC meeting</td>
<td>Ratified PBAC Minutes for deferred and not recommended submissions by email (Sections 7.1.2 and 7.1.3)</td>
</tr>
</tbody>
</table>

7.1.1 Receipt of positive recommendation

For a positive recommendation, written advice (referred to as the PBAC Minutes) is provided to the sponsor 15 working days after each PBAC meeting. These Minutes provide the basis and rationale for the PBAC outcomes.

The sponsor can accept the PBAC’s recommendation. Refer to Section 8 for the requirements of listing a medicine on the PBS.

The sponsor can decide to not accept the PBAC recommendation. Section 7.1.3 sets out the sponsor’s options in this situation.

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 sponsor 25 working days after the PBAC meeting.

7.1.3 Receipt of a decision to not recommend

Where the PBAC decides to not recommend a submission, written advice (referred to as the PBAC Minutes) is provided to the sponsor 25 working days after the PBAC meeting. This also provides the basis and rationale for the PBAC outcomes.

Sponsors can make another submission to the PBAC (referred to as a resubmission). Information about resubmissions is located in the PBAC Guidelines for preparing submissions to the PBAC. Where the PBAC has already considered a major submission, any resubmission is usually required in the form of a major submission; however, in certain circumstances, in liaison with the PBAC Chair or the department, a minor submission may be accepted.

Sponsors can meet with the PBAC Chair to develop a greater understanding of the PBAC decision to not recommend a major submission (see Section 7.1.5).

Sponsors may seek an independent review of the PBAC decision, if eligible (refer to Section 7.2).
7.1.4 Preparation for resubmission

Sponsors seeking to prepare a resubmission are eligible for a presubmission meeting with PEB officers if:

- the outstanding issues raised in a resubmission require a substantial rewrite of the submission evidence or revision of the model, and further technical advice from the department would provide useful input that cannot be obtained from another source
- the sponsor is proposing a complex RSA that is integral to the consideration of the PBAC (refer to Section 8.4)
- the sponsor is proposing an MAP that involves prospective collection of evidence as per the [draft Managed Access Program Framework](#).

Refer to Section 4.5 for additional information on, and links to dates allocated for, presubmission meetings.

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

Sponsors 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.

Sponsors should email the department to request a meeting (refer to Appendix A for contact details). The dates of these meetings are not set in the calendar of dates. PEB aims to hold these meetings before the date for receipt of minor submissions to the next PBAC meeting.

Meetings are usually 30 minutes in duration. Officers from PEB may also attend as requested by the PBAC Chair.

The PBAC Chair and departmental officers do not keep records of the issues discussed at the meeting.

Refer to Section 4.5 regarding attendees and conduct of the meeting. An agenda paper is not usually required, because the PBAC Minutes are considered the agenda papers; however, sponsors may provide a brief document to assist discussion.

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

The PBAC has published its decisions since June 2003, excluding advice related to price only.

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, 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 the Friday afternoon at week six 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

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

Sponsors have one to two working days to review the outcome statements. For medicines that the PBAC did not recommend or deferred making a recommendation on, the sponsor is asked to provide a comment, which is published with the outcome statement. Sponsors provide their comments by email (refer Appendix A for contact details).

If the sponsor believes that the PBAC Outcome has factual errors, the sponsor 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

PSDs provide the public with information about PBAC decisions, and the basis and rationale for each decision. The aim is for stakeholders (including health professionals and patients) to be informed of the rationale for specific PBAC outcomes.

The availability of PSDs is the result of initiatives coming out of the AUSFTA, and is based on transparency principles supporting the provision of information regarding the basis for the subsidy of pharmaceuticals to the Australian community through the PBS. PSDs are published around four months after the relevant PBAC meeting (see Section 7.4.2).

7.4.1 Preparing the Public Summary Documents

The PBAC publishes a PSD for each submission for listing one or more medicinal/vaccine products on the PBS/NIP, except for submissions where pricing issues are the only matter considered by the PBAC.

PSDs are prepared by departmental officers reflecting the PBAC Minutes. The evidence presented in the submission, and the PBAC’s view of the evidence, is outlined in the PSD.

The purpose of the PSD is to provide consistent information for all PBAC outcomes for medicines. As the PBAC is required by legislation to take into account the effectiveness and cost of medicines proposed for subsidy compared with other therapies, the PSD includes information on the economic
analysis and expected use. Some of the information presented in PSDs is subject to confidentiality considerations. The structure and confidentiality requirements of PSDs, and those submissions that do not have a PSD prepared, are subject to ongoing negotiations with pharmaceutical representative organisations such as Medicines Australia.

More information about the PSD structure is available on the PBS website.

The steps for the preparation and publication of PSDs are:

1. Ratified minutes from the PBAC meeting form the basis of the PSD. Departmental officers redact the results of clinical trial data or other clinical studies that are not in the public domain, and the price offered for the medicinal products in the minutes.
   - Where significant portions of a data table require redaction, a descriptive paragraph must follow the table to provide sufficient context to the reader.
   - Departmental officers replace the following with a standardised agreed range
     ▪ incremental cost-effectiveness ratio or other measure of the value proposed in the submission
     ▪ estimated cost of supplying the medicinal/vaccine product through the PBS/NIP
     ▪ estimated number of patients and number of packs supplied
     ▪ budget impact of listing.

2. The draft PSD is emailed to the sponsor’s designated contact or authorised representative. The sponsor has an opportunity to review and request any changes to the PSD it considers appropriate for understanding the information contained in the draft PSD and maintaining the sponsor’s commercial confidentiality. The sponsor is asked to provide sufficient justification to have additional content redacted. The revised draft PSD is emailed to the department within 10 working days of receipt (refer to Appendix A for contact details).

3. Departmental officers review the revised draft PSD. The department must ensure that the PSD reflects the PBAC Minutes. It must also be in line with the transparency principles in the National Medicines Policy, which states that consumers and health practitioners should be encouraged to understand the costs, benefits and risks of medicines/vaccines.

4. Where departmental officers form the view that the sponsor’s requested changes conflict with the requirement for consistency with the PBAC Minutes and are not in line with the transparency principles, departmental officers negotiate with the sponsor. The sponsor is asked to provide further evidence or justification for the requested changes. All negotiations for a specific PSD should be concluded two weeks before the expected publication date for the PSD.

The department is responsible for the final clearance of PSDs. The Assistant Secretary, PEB, will agree the content for publication on the PBS website. If a sponsor considers it has reached an impasse regarding the content of a PSD, the sponsor can seek further discussions with the First Assistant Secretary or Deputy Secretary responsible for PBD and the Chief Executive Officer of Medicines Australia. A copy of the finalised PSD is provided to the sponsor’s contact or authorised representative the day before publication on the PBS website.
7.4.2 Timeframe for Public Summary Document publication

Table 7.2 shows the timeframe for publishing PSDs.

Table 7.2  Timeframe for the publication of Public Summary Documents

<table>
<thead>
<tr>
<th>Type of submission</th>
<th>Time for publication (after the PBAC meeting)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submissions recommended</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Second or subsequent submissions (resubmissions) that were not recommended</td>
<td>16 weeks</td>
</tr>
<tr>
<td>First submissions where the PBAC did not recommend or deferred making a recommendation</td>
<td>18 weeks</td>
</tr>
<tr>
<td>Second or subsequent submissions (resubmissions) where the PBAC deferred a recommendation</td>
<td>18 weeks</td>
</tr>
</tbody>
</table>

For submissions made under the TGA–PBAC parallel process, PSDs will be prepared following standard timelines but will not be published until TGA registration has occurred.

7.4.3 Management of documentation

A specified departmental officer is assigned to prepare PSDs and negotiate with the sponsor.

All documentation is electronic and communication is via email.

PSDs conform to the Level AA accessibility requirement of the Web Content Accessibility Guidelines 2.0.
8 Procedures for a positive recommendation to list

Following a positive PBAC recommendation to the Australian Government Minister for Health to list a medicine on the PBS schedule, there are several activities the sponsor needs to complete and documents that must be submitted before the medicine can be recommended to the minister for listing. Each step must be completed in time for preparing and signing the legislative instruments and publication of the schedule on the PBS website.

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.

The activities and documents that need to be completed by the sponsor are:

- 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 8.1.
- Agreement on the expected utilisation and financial (budget) cost to the Australian Government. Refer to Section 8.2.
- Agreement of the restriction wording to be published on the PBS and RPBS schedule and in the listing instrument. Refer to Section 8.3.
- Establish a deed of agreement or other documentation related to a MAP, RSA and special pricing arrangement (SPA) if required. Refer to Section 8.4.
- Letter of application. Refer to Section 8.5.1.
- Assurance that the product will be available for supply on the date of listing. Refer to Section 8.5.2.
- Declaration of Responsible Person. Refer to Section 8.5.3.
- Application to list a medicine as a pharmaceutical benefit (pb11). This is provided in submission documentation. Refer to Section 5.

8.1 Price agreement

A price agreement or determination must be made for all brands of a pharmaceutical item to be listed on the PBS.

The price for a new listing is negotiated after the sponsor receives the PBAC Minutes explaining the PBAC’s recommendation to the minister.

Once negotiations have been completed and a price has been agreed in principle between the sponsor and the department, the sponsor should provide the department with a completed and signed pb11a form, called a ‘Request for approved ex-manufacturer price’ form. These are forwarded to the department by email or post (refer to contact details in Appendix A).

Agreement in principle of the price of the medicinal product to be listed is required before commencement of the revision of estimates of expected utilisation and financial impact (Section 8.2) and any deed negotiations (Section 8.4).
Where a sponsor seeks an SPA, and the department indicates it is prepared to recommend an SPA to the minister, then agreement in principle needs to be reached on both the published and effective price before the start of the revision of estimates of expected utilisation and financial impact and any further deed negotiations. Arrangements for an SPA are established through a deed of agreement (refer to Section 8.4.1).

8.1.1 Cost of goods (pb11b)

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

8.1.2 Price agreement timeframes

The deadlines and related effective dates are published in the PBS calendar.

8.2 Finalisation of the budget impact

The PBAC considers Section 4 (estimates of use and financial cost) 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 financial model structure and inputs to ensure this is accurate and complete.

The finalised model of use through the PBS and the RPBS is provided to each sponsor of the medicine for review, comment and clarification. The sponsor is required to agree to the estimates of use and cost. Where a sponsor 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 sponsor documenting agreement of the:

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

Following the sponsor’s agreement, the financial model is circulated to other areas of the Department of Health (eg 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).

8.2.1 Review of budget impact

The department reviews estimates of use and costs following the PBAC’s recommendation. The reviewed financial model is provided to sponsors.

Sponsors are given up to five business days to review and comment on the estimates of utilisation and financial impact. If a sponsor 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.

Following agreement of the estimates of utilisation and financial impact between the departmental officer and the sponsor, 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.

8.2.2 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, the Department of Human Services 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.

8.3 Restriction wording

The PBAC is required, as part of its advice to the minister, to recommend any restriction on the circumstances for prescribing that should apply to a new listing. The wording of the restriction must be finalised before listing on the PBS Schedule can be recommended to the minister.

The final restriction will generally be provided to the sponsor in the PBAC Minutes. In some cases, where refinement of the wording is requested by the PBAC, the PBAC Minutes state that the restriction is ‘to be finalised’.

Where the PBAC has not finalised the restriction, the Department of Health’s Restrictions Working Group may meet to discuss the wording to ensure it reflects the intention of the PBAC. Departmental officers, working with the Restrictions Working Group and the PBAC out of session, prepare a draft version of the restriction. Where appropriate, clinical specialists may be consulted (refer to Section 6.8). The draft is provided to the Department of Human Services to check for issues with administration. The completed draft is provided to the sponsor for comment.

In these instances, the sponsor is required to agree to the wording of the restriction in writing before the listing can be recommended to the minister. This can be via company email to the PBAC Secretariat. The PBAC ratifies the restriction at the next opportunity. This is usually during the next meeting.

8.3.1 Restriction wording timeframes

When a final restriction is available, a copy of the restriction wording that will be recommended to the Minister for Health is provided to the sponsors with the ratified PBAC Minutes three weeks after the PBAC meeting.

When the PBAC Minutes indicate the restriction wording is ‘to be finalised’, the restriction will be forwarded to the sponsor for comments. The sponsor is able to comment on and discuss the restriction with the department. If the sponsor agrees to the restriction wording, the sponsor should forward agreement by company email to the PBAC Secretariat. Refer to Appendix A for contact details.

In the event that the sponsor does not agree with the restriction wording in the PBAC Minutes or the draft restriction provided by PEB officers, the listing will not proceed. Where the department and the sponsor are unable to resolve differences about the restriction wording, these restriction
wring issues may need to be referred to the PBAC through a new submission (see Section 5). Refer to Appendix A for contact details.

8.4 Preparation 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.

Sponsors 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 Australian Government Department of Health.

8.4.1 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 sponsor as soon as possible after the estimates of utilisation and financial impact have been considered by the Department of Finance. Where the sponsor enters into the same therapeutic market as an already listed medicine, the sponsor 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 sponsor has up to 10 working days to respond. If more time is required, an extension can be requested by email to the contact officer in the Department of Health.

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 sponsor.

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 sponsor. The letter will also provide additional documentation explaining the basis for the monies owing and the date monies are due.
8.4.2 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 sponsor, advising them of the outcomes of any review of the deed.

If sponsors 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.

8.5 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).

8.5.1 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 sponsor. 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 a sponsor 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 8.5.2)
- a responsible person form (see section 8.5.3).

For contact information, refer to Appendix A.

8.5.2 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.

8.5.3 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 PEB 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).

8.6 Notification of listing on the PBS

A PBS listing decision is made when the relevant legislative instruments are signed by the minister (or a delegate of the minister) and registered on the Federal Register of Legislative Instruments. A listing takes effect on the date specified in those instruments.

Stakeholders who have a business requirement to know in advance, such as sponsors of the medicine, are advised that a listing has been recommended to the minister (or delegate) around one month in advance of the proposed date of effect.

8.7 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, the Office of Health Protection will seek approval from the Australian Government to fund the vaccine under the NIP.

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

The Office of Health Protection 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  Review of PBS listings

The PBAC and the minister can request reviews of medicine use, cost-effectiveness and other aspects of quality use of medicines of PBS-listed medicines. This includes postmarket reviews (see Section 9.2), cost-effectiveness reviews, and reviews of the utilisation of specific medicines or groups of medicines listed on the PBS.

9.1  Drug Utilisation Sub-Committee review

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

9.1.1  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 sponsor 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. Sponsors are notified at least ten weeks before a DUSC meeting if a report on the use of a medicine they sponsor will be considered.

Sponsors are provided with the DUSC reports on the utilisation of medicines four weeks before the DUSC meeting (PBAC week 8). Each sponsor 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 sponsors and other relevant stakeholders at the DUSC meeting.

Each sponsor 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 postmarket review is warranted (refer to Section 9.2).

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

9.1.2 Publication of DUSC reports

Publication of the DUSC reports started in 2014 and is now a routine process. The DUSC public release documents provide public access to DUSC utilisation analysis reports.

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

The DUSC public release document is sent to each relevant sponsor 15 weeks after the DUSC meeting. Sponsors 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 sponsor depending on the nature of the proposed comments and redactions. The Secretariat provides the finalised public release document to the sponsor at the end of the three weeks. The DUSC report is published on the PBS website two weeks later.

9.2 Postmarket reviews

The Australian Government has introduced a systematic postmarket approach to monitoring medicines in use to inform decision making.

Postmarket reviews of PBS-listed medicines reviews 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 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 continuing monitoring clinical and cost-effectiveness of medicines after they have been listed on the PBS.
9.2.1 Ministerial approval for a postmarket review

A full postmarket review will only proceed following ministerial approval.

Postmarket 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.

Postmarket 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 postmarket reviews.

9.2.2 Postmarket review processes

Postmarket reviews are conducted in accordance with a consultative framework that is agreed to by the pharmaceutical industry representative body (Medicines Australia) and the department.

9.3 PBAC commissioned reviews of listed medicines

The PBAC may request a focused review of one or more aspects of PBS-listed medicines.

These reviews are conducted in a collaborative and consultative manner, following similar processes to postmarket reviews. These usually have a narrow focus such as examination of cost-effectiveness following release of new evidence, or determining the cost-effectiveness of a listed medicine in a specific group of people.
Appendix A Information sources and contacts

The following information sources and contact details for areas within the Australian Government Department of Health may be useful to sponsors 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](http://pbs.gov.au), 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
Pharmaceutical Evaluation Branch MDP910
Department of Health
GPO Box 9848
Canberra ACT 2601
Email PBAC: [pbac@health.gov.au](mailto:pbac@health.gov.au)

Email PBAC Secretariat: [pbac@health.gov.au](mailto:pbac@health.gov.au) for matters related to:

- the Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee
- 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 presubmission meetings and post-PBAC meetings with the Chair

For all matters related to PBAC meetings:
Email PBAC Secretariat: secretariat.compliance@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
Pharmaceutical Benefits Division MDP 952
Department of Health
GPO Box 9848
Canberra ACT 2601
Email: pbscostrecovery@health.gov.au

A.2.4 Submission lodgment

Contact for submissions to the PBAC:
Mail: PBS Submissions
MDP 903
23 Furzer Street
Phillip ACT 2611
Email: PBSsubmissions@health.gov.au

A.2.5 Consumer comments on the PBAC Agenda

PBAC Secretariat
Pharmaceutical Evaluation Branch MDP910
Department of Health
GPO Box 9848
Canberra ACT 2601
Email commentsPBAC@health.gov.au

A.2.6 Matters relating to confirming the price and other post-PBAC recommendation matters

Contact the Pricing Section 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 lodgment of pb11a, and pb11b after the PBAC recommendation:
General 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.

A.2.7 Matters relating to estimates of utilisation and financial impact

Email Estimates Section: pbsestimates@health.gov.au
A.2.8 Matters relating to establishment of a Deed
Email PBS Deeds team: pbspricing@health.gov.au

A.2.9 Matters relating to documents for lodgment of new brand of existing pharmaceutical item submissions not requiring PBAC advice, responsible person 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 and supply issues:
Email PBS Listing: pbslisting@health.gov.au

A.2.10 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.2.11 Economics Sub-Committee (ESC) Secretariat

Contact for matters considered by the Economics Sub-Committee:
Email ESC: esc@health.gov.au

A.2.12 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

A2.13 ATAGI and the National Immunisation Program

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

A2.14 HTA Access Point

For sponsors requiring information on preparing integrated codependent submissions:

Department of Health
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 HTA website