Australian Government
Department of Health

2024 PBS Post-market Review Framework

Information for Stakeholders

Contents

Abbreviations

Abbreviation	Full Name / Wording
COIs	Conflicts of interest
DUSC	Drug Utilisation Sub-Committee
ESC	Economics Sub-Committee
HTA	Health Technology Assessment
MA	Medicines Australia
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PMR	Post-market Review
PSCR	Pre-Sub-Committee response
ToRs	Terms of Reference

Background

In 2011, the Australian Government introduced Pharmaceutical Benefits Scheme (PBS) Post-market Reviews (PMRs) as a systematic approach to monitoring medicines following PBS listing, to inform decision making relating to ongoing access and subsidy. PMRs provide evidence and options to the Pharmaceutical Benefits Advisory Committee (PBAC) to ensure patient safety, quality use of medicines and the ongoing cost-effective use of PBS-listed medicines.

PMRs 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.

PMRs were established under the 2011-12 Budget measure *Improving sustainability of the PBS through enhanced post-market surveillance*.

The PMR program was established to contribute to:

- Ensuring the ongoing viability of the PBS through targeted medicines usage and avoiding preventable wastage or inappropriate prescribing.
- A better understanding of medicines utilisation, to review intended clinical benefit and inform medicines evaluation processes.
- Ongoing cost-effectiveness, including through better management of clinical and economic uncertainty.
- Overall improvements to the quality use of medicines and education for patients and health professionals.

Details of current and completed PMRs are available on the PBS website.

In 2022, the PMR Framework was reconsidered in the context of the new Strategic Agreement between the Commonwealth and Medicines Australia (MA).

Under the Strategic Agreement, the Commonwealth and MA agreed to:

> "*Work together with other relevant stakeholders to improve the current PMR Framework with the goal of reducing the timeframe from PBAC recommendation of the commencement of a Review, to completion of the Review, to a timeframe of within 12 months, subject always to the Framework not limiting PBAC independence*."

A draft revised PMR Framework was published for public consultation from 20 October 2022 to 16 December 2022. The final 2024 PMR Framework, as outlined in this document, was developed by the Department of Health and Aged Care in consultation with MA and considered stakeholder comments received as part of the consultation process. The 2024 PMR Framework was endorsed by the PBAC in December 2023 and approved by the Minister for Health and Aged Care ("the Minister") in January 2024.

Introduction

When a medicine is recommended for PBS listing, the PBAC's advice is made in the context of the treatments and evidence available at that point in time. Over time, new medicines may be developed and subsidised, more data on safety and efficacy may become available and treatment guidelines may change. As a result, the actual use and/or benefits of a medicine may change and may no longer reflect the evidence considered by the PBAC at the time of recommendation for listing.

The PMR Framework provides a mechanism for medicines to be re-considered in the current treatment context. It provides a transparent and formal approach to the ongoing evaluation of medicines subsidised by the Australian Government through the PBS. This includes consideration of actual utilisation, comparative efficacy/effectiveness, comparative safety, cost-effectiveness, treatment guidelines, health benefits and consumer experiences. As a result, the PMR Framework allows for measures to be implemented to address concerns around how a medicine is used that may have arisen since the time of PBS listing such as, improving education around medicines and their use, or revising PBS subsidy arrangements.

PMRs are overseen by the PBAC and its sub-committees. Further information regarding the PBAC and its sub-committees is provided below.

Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC is an independent expert body appointed by the Australian Government and is comprised of doctors, health professionals, health economists and consumer representatives. The PBAC is responsible for evaluating the clinical and cost-effectiveness of medicines in order to make recommendations relating to listing on the PBS. Recommendations for new listings are informed by evidence of a medicine's clinical effectiveness (how well it works), safety, and cost-effectiveness ('value for money') compared with other treatments.

The PBAC has a broad statutory function under the *National Health Act 1953* (the Act), to advise the Minister on any matters concerning the operation of the PBS, which includes making further recommendations regarding the safety, effectiveness, and cost-effectiveness of medicines after they have been listed. Therefore, the PBAC also considers the need for, and provides recommendations on PMRs.

The PBAC meets regularly throughout the year, per the PBS calendar, to consider applications for funding new medicines. The PBAC Executive is comprised of the Chair and Deputy Chair of the PBAC, the Chair of the Drug Utilisation Sub-Committee (DUSC), the Chair of the Economics Sub-Committee (ESC), and a consumer nominee from the PBAC. The PBAC Executive meets in the lead up to each regular PBAC meeting to review less complex submissions such as category 3, category 4, and committee secretariat submissions, and to consider other matters.

The PBAC has two sub-committees to assist with analysis and advice in these areas: the DUSC and the ESC.

Additional information relating to the PBS, PBAC meeting dates, agendas and outcomes is available on the PBS website.

Drug Utilisation Sub-Committee (DUSC)

The DUSC assesses estimates on projected usage and the financial cost of medicines to be considered for listing on the PBS. It also collects and analyses data on the actual use of PBS-listed medicines (including in comparison with other countries).

New medicines on the PBS are routinely monitored by the DUSC 24 months after listing. Monitoring may include analyses to examine the actual use of a medicine and medicine utilisation trends in comparison to the predicted usage when recommended by the PBAC and listed on the PBS. The DUSC can also analyse the utilisation of a class or category of a medicine, or a group of medicines that are used to treat a particular condition and compares these with the basis of PBS listings. These analyses can highlight medicines use issues that need to be considered by the PBAC, which may result in a recommendation for further research and consultation according to the PMR Framework.

The DUSC meets three times a year, in February, June and October, and is constituted by a broad range of experts, such as clinicians, academics, a consumer representative and an industry representative from MA.

Additional information relating to the DUSC is available on the PBS website.

Economics Sub-Committee (ESC)

The ESC of the PBAC assesses clinical and economic evaluations of medicines submitted to the PBAC for listing and advises the PBAC on the technical aspects of these evaluations.

Clinicians and academics with relevant expertise, and an industry representative from MA, are members of the ESC. The ESC meets the week following the DUSC, three times a year.

Additional information relating to the ESC is available on the PBS website.

Additional information

Public announcements and general PMR Framework information for each PMR will be communicated on the Post-market Review webpage and via PBS News Updates.

Stakeholders are encouraged to subscribe to PBS News Updates for the latest information and to be advised of the timing and processes for each PMR.

Information on consultation processes for medicines and vaccines can be viewed at the Office of Health Technology Assessment (OHTA) consultation hub.

How can I get involved?

All PMRs follow a standard approach, which includes public consultation at various stages throughout the Review process in order to provide stakeholders with a number of opportunities to input.

Stakeholders may raise medicine related issues, potential topics for future PMRs, and suggestions for improvements to the 2024 PMR Framework by emailing PBSpostmarket@health.gov.au at any time.

2024 Post-market Review Framework

The 2024 PMR Framework described in this document relates to PMRs for medicines listed on the PBS. However, PMRs may be conducted for a range of other health technologies and health-related initiatives, policies, and programs. Without limiting the independence of the PBAC, it is intended that a PMR will follow the 2024 PMR Framework outlined in this document whenever the PBAC makes a formal recommendation for a PMR to proceed.

The Framework described in this document (as illustrated at Figure 1 and Figure 2), outlines the steps in a PMR and estimated timeframes.

Figure 1 illustrates the activities preceding a PMR. This includes the PBAC's consideration of the PMR workplan (see PBAC consideration of the PMR workplan for further details) through to PBAC Executive approval of the Review Terms of Reference (ToRs).

Figure 2 illustrates the PMR process once the ToRs are approved and Review activities commence. This includes the steps from when the Review is announced online, through to PBAC consideration of the draft PMR report and the post-review implementation process.

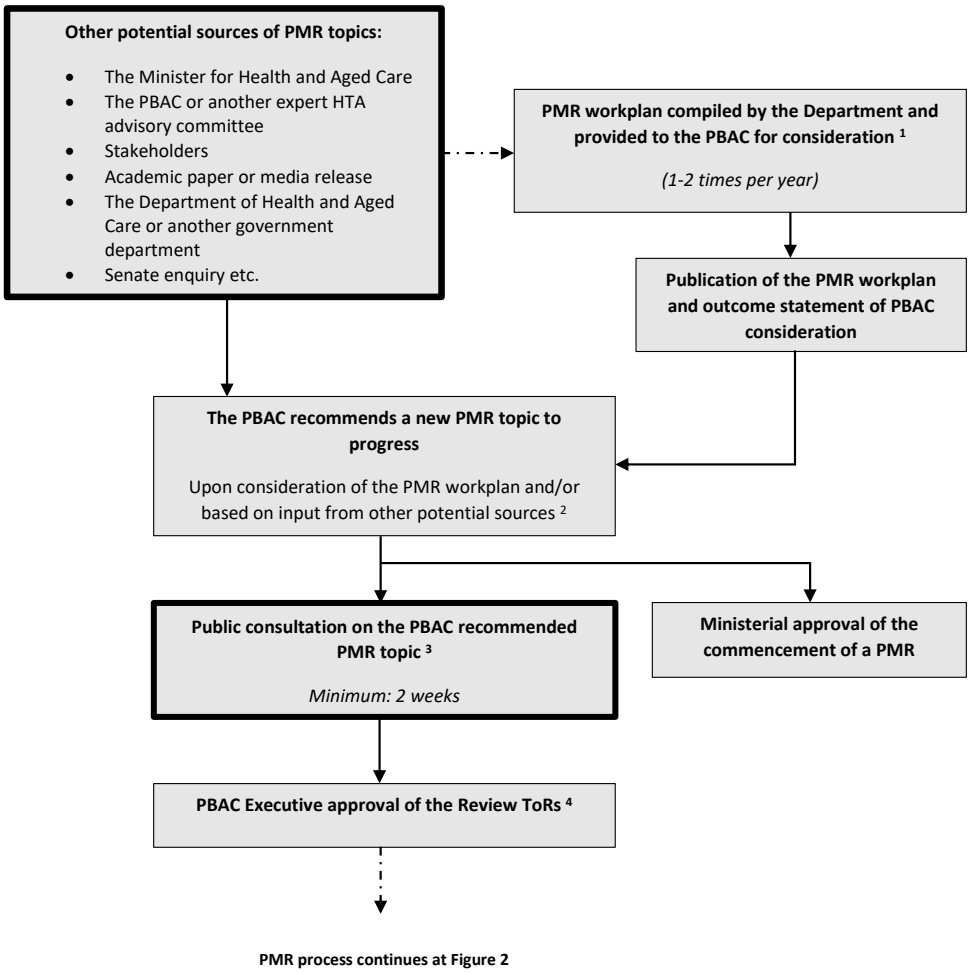
According to the Framework outlined in this document, a PMR is considered to have commenced when the Review is announced online following PBAC Executive approval of the Review ToRs.

The PMR Framework is not intended to be prescriptive, as PMRs will differ in their complexity and focus. The Framework promotes consistency in approach, while providing the flexibility necessary to accommodate the different requirements of each Review.

The estimated time for completion of key PMR milestones, from announcement of the Review online to PBAC consideration of the draft PMR report, is approximately 52 weeks (Figure 2). Information on timeframes for each PMR will be communicated via PBS News Update and published on the Post-market Review webpage as it becomes available. Consumers, health professionals and any other interested groups or organisations can provide input to PMRs by visiting the Office of Health Technology Assessment (OHTA) consultation hub.

An ongoing PMR does not interrupt or prevent the submission processes for seeking subsidy of new or amended listings of medicines on the PBS. However, new medicines that are recommended for PBS listing during the course of a PMR may be affected by any subsequent recommendations arising from the Review.

Figure 1. Activities preceding a Post-market Review

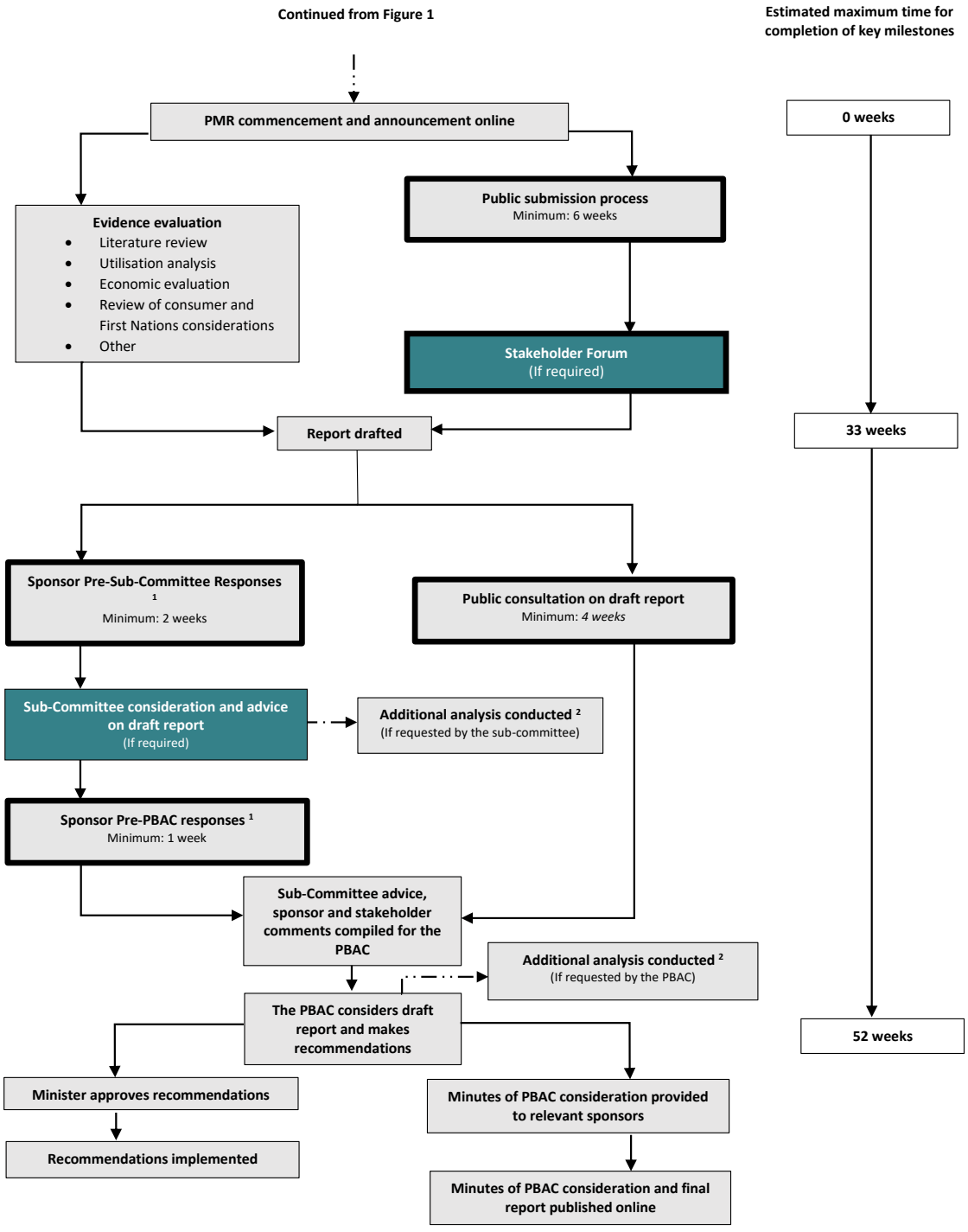


Abbreviations: HTA = Health Technology Assessment; PBAC = Pharmaceutical Benefits Advisory Committee; PMR = Post-market Review; ToRs = Terms of Reference.

1. Information in the PMR workplan may be based on prior input from 'other potential sources' (as indicated by the dashed line between the top two boxes in the figure above).
2. The PBAC may recommend a new PMR topic to progress based on the information detailed in the PMR workplan or based directly on input received from 'other potential sources.' This means that not all PBAC-recommended PMRs will arise from consideration of the PMR workplan.
3. As part of this consultation step, sponsors/stakeholders will be invited to provide general comments on the PBAC-recommended PMR topic in addition to the following:
    - Whether a stakeholder forum should be held as part of the recommended PMR and the timing of the forum; AND
    - Identify any potential sources of evidence to inform the PBAC-recommended PMR topic.
4. The PBAC Executive will also consider previous sponsor/stakeholder input and be asked to advise on the need for a stakeholder forum and the timing of the forum as part of the recommended PMR at this step.

Note: A box with a thick border indicates an opportunity for sponsor/stakeholder input into the PMR process.

Figure 2. Post-market Review Process



Abbreviations: PBAC = Pharmaceutical Benefits Advisory Committee; PMR = Post-market Review.

1. Sponsors of the medicines included in the PMR will be provided with a copy of the draft report along with the economic model (if applicable) to assist in the preparation of a Pre-Sub-Committee Response (PSCR)/Pre-PBAC response.
2. Where the PBAC and/or a sub-committee requests that additional analysis is conducted, the PMR may not be completed within a timeframe of 52 weeks. The sub-committee may request that the additional information is resubmitted to the same sub-committee for consideration at a later date, a different PBAC sub-committee, or provided directly to the PBAC. Where the PBAC requests that additional analysis is conducted, it may request that the additional information is resubmitted directly back to the committee or a sub-committee for consideration at a later date. Relevant sponsors will be provided with any additional information/analyses once completed and will be invited to submit a PSCR and/or pre-PBAC response.

Notes:

- A box with a thick border indicates an opportunity for sponsor/stakeholder input into the PMR process.
- A blue/green coloured box indicates an optional step in the PMR process that will only proceed if required.
- The Department will form a Review Reference Group if requested by the PBAC/PBAC Executive. For further information refer to the 'Reference Group' section of this document.

Activities preceding a Post-market Review

Sources of potential Post-market Reviews

A PMR may involve a single medicine, a class or category of medicines, or multiple classes of medicines that are used to treat a particular condition. PMRs may be initiated at any time, and be triggered by a number of issues including, but not limited to:

- clinical efficacy and safety
- use that is inconsistent with treatment guidelines and emerging clinical data
- use outside of PBS listing restrictions/subsidy arrangements
- cost-effectiveness.

These issues can be identified through a number of sources, including:

- stakeholders such as clinicians, patients, and industry
- the PBAC (or a PBAC sub-committee)
- a request by the Minister
- an academic publication or media release
- a Health Technology Assessment (HTA) evaluation group
- another area of the Department such as the Therapeutic Goods Administration (TGA), Services Australia, or another government department/agency
- a Senate Inquiry.

The PBAC may request preliminary research or evidence on an issue to inform its consideration of potential PMR topics. Research may be conducted internally or contracted to independent external providers with demonstrated subject matter and technical expertise, selected from a panel of experts maintained by the Department. Outcomes of this research, such as a literature review or an analysis of utilisation, will be provided to the PBAC (or sub-committee) to support the PBAC's (or its sub-committee's) consideration of potential PMR topics.

PBAC consideration of the PMR workplan

All PMR topics that are recommended by the PBAC will be documented in the PMR workplan, which will be provided to the PBAC for consideration periodically (1--2 times each year). This will be an opportunity for the PBAC to have visibility of the status of existing PMRs and to consider any new topics that have been proposed by stakeholders and/or the Department.

The workplan will detail issues that have been identified relating to the medicine(s) of interest and the rationale for proposing any new topics. Additional information relating to the medicine(s) of interest may also be documented in the PMR workplan to assist the PBAC in deciding whether to recommend a new PMR. This information may include a summary of current PBS restrictions and/or TGA-approved indications; a

summary of treatment guidelines; a preliminary analysis of PBS utilisation; and any previous PBAC or sub-committee recommendations/advice relevant to the identified issues. Indicative timeframes for the completion of PMRs will also be included in the workplan and updated on the Review webpage as the PMR progresses.

The PMR workplan and PBAC outcome statement will be published on the PBS website following consideration by the PBAC, to ensure that stakeholders have visibility of the status of all PMRs.

Recommendation for a Post-market Review by the PBAC

As detailed above, the Department will provide information on potential PMR topics to the PBAC as part of the PMR workplan. The PBAC may also consider potential PMR topics at any time, including in response to correspondence received by the Committee or in response to issues raised in considering submissions.

The PBAC will prioritise PMR topics and make a recommendation on the PMRs to be progressed based on a range of factors including, but not limited to:

- urgency relating to a safety concern
- urgency relating to a quality use of medicines concern
- urgency relating to a gap in service provision, e.g., where there is new evidence which could lead to an expansion of a service or funding (or the converse)
- urgency relating to patient or consumer need
- potential impact to the health budget
- data availability to investigate the identified issues
- the ability of the Department and the PBAC to resolve identified issues
- the priorities of the Australian Government and the Department.

An extract of the minutes that include the PBAC's consideration of the PMR topic and any resulting recommendation to undertake a PMR, will be provided to relevant medicine sponsors. This will serve as an early notification that a PMR topic has been recommended by the PBAC and will commence when, and if, the Minister agrees.

Ministerial approval of the Review's commencement

Following a PBAC recommendation for a PMR to commence, the Minister will be asked to approve a PMR topic prior to the commencement of the Review. Relevant sponsors will be advised of the Minister's decision.

Public consultation on the PBAC-recommended PMR topic

Following a PBAC recommendation for a PMR to commence, a two-week public consultation process will be held. As part of this consultation process stakeholders and sponsors will be given an opportunity to provide general comments on the PBAC-recommended PMR topic, in addition to the following:

- whether a stakeholder forum should be held as part of the recommended PMR topic and the timing of the forum within the PMR process.
- identify any potential sources of evidence to inform the PBAC-recommended PMR topic.

Approval of the Review Terms of Reference (ToRs) by the PBAC Executive

The ToRs for each PMR outline the key issues and guide the focus of the Review and the research questions to be addressed in collating the evidence.

The five potential ToRs for each PMR are standardised in the 2024 PMR Framework and are detailed below. PMRs may include one or more of the standard ToRs depending on the issue raised. ToRs 1-4 have been included in the majority of previous PMRs. A new consumer focussed ToR 5 has been included based on advice from the HTA Consumer Consultative Committee, to better understand the patient experience with the medicine(s) of interest, including issues specific to First Nations peoples. It should be noted that not all standard ToRs will be undertaken for every PMR. For example, where the PBAC requests information relating only to the utilisation of a medicine(s), ToR 2 may be the only ToR required to address the research question(s) of interest. The PBAC may request for ToRs to be undertaken in parallel, or sequentially and subject to its consideration of findings, e.g., a cost-effectiveness review may be requested after evidence on utilisation, efficacy and/or safety has been considered by the Committee.

ToR 1 – Review of clinical guidelines

Collate the current clinical guidelines for the medicine(s) of interest and compare these to the TGA-approved indications and PBS restrictions for these medicines.

ToR 2 – Utilisation review

Analysis of medicine utilisation data provides information on how the medicine(s) of interest are being used in practice. Specifically, these analyses can provide information relating to:

- patterns of use (including adherence, persistence, prevalence, incidence, co-prescribing/combination use, switching between alternative therapies, and use of other medicines prior to or following initiation)
- adherence to treatment guidelines and PBS restrictions
- patient access across geographical regions
- other outcomes associated with use of the medicine(s), such as use of other medicines that may be used to treat adverse events
- the conditions medicines are being prescribed/recommended to treat.

The most used source of data for analyses of medicine utilisation in Australia is the PBS dataset. Additional data sources may also be used to establish a more complete picture of prescribing and use in Australian clinical practice. These include but are not limited to:

- Australian Bureau of Statistics (ABS) National Health Survey
- Medicare Benefits Schedule (MBS) data
- MedicineInsight prescriber data
- samples of prescriber activity
- disease registries
- Australian Institute of Health and Welfare (AIHW) linked datasets.

ToR 3 – Review the literature with respect to the efficacy and safety of the medicine(s) of interest

The scope of each literature review is dependent on the requirements of the PMR. There is usually a focus on the most recent clinical evidence that the PBAC has not previously considered. The literature review may focus on one, or a combination, of the following areas:

- efficacy of the medicine(s)
- comparative efficacy between medicines used to treat the condition of interest
- safety of the medicine(s)
- comparative safety between medicines.

ToR 4 – Cost-effectiveness review/economic evaluation

An economic analysis may be conducted as appropriate. This analysis may assess the impact of actual use, or the impact of proposed changes to use, on the cost-effectiveness of the medicine(s) under review.

Revised or new economic modelling may be required if there is new evidence available that would change previous assumptions used in the cost--effectiveness model(s) considered by the PBAC.

ToR 5 – Consumer and First Nations considerations

Seek public submissions and/or review the published evidence on the patient experience with the medicine(s) of interest from the perspective of consumers. This may include a review of the efficacy, adverse effects and any access issues that impact specific patient groups including First Nations people.

Under the 2024 PMR Framework the PBAC Executive will be requested to approve the final Review ToRs in most cases. However, where there is significant deviation from the standard ToRs for a recommended PMR, the advice on, and approval of, the ToRs by the broader committee will be sought.

In considering the Review ToRs, the PBAC Executive will be provided with sponsor/stakeholder input from consultation on the PMR topic and be asked to advise on the need for, and the timing of, a stakeholder forum

Post-market Review process

PMR commencement and announcement online

Once the PBAC Executive has approved the Review ToRs, the Review will be posted on the Post-market Review webpage and announced via a PBS News Update. Relevant sponsors and stakeholder groups will also be notified of the commencement of the PMR directly via email. A PMR is considered to have commenced upon its public announcement.

Stakeholder communication

There are four key opportunities for stakeholders to provide input during the PMR process as follows:

- the consultation process on the PBAC-recommended PMR topic
- the Public submission process addressing the PMR
- a Stakeholder forum (if required)
- comments on the draft PMR report (see Stakeholder consultation on the draft report for further details).

In addition to this:

- Where the draft PMR report is to be provided to a PBAC sub-committee for advice, relevant sponsors are able to provide a Pre-Sub-Committee response (PSCR) (see Sub-committee consideration of the draft report for further details) to be considered by the sub-committee alongside the draft report.
- Relevant sponsors are also given the opportunity to respond to sub-committee advice prior to PBAC consideration of the draft report in the form of a pre-PBAC response.

Role of the Department of Health and Aged Care

The Technology Assessment and Access Division in the Department is responsible for the management of PMRs. This includes, but is not limited to:

- managing the process for identifying PMRs, either through the PBAC or other processes
- providing background information on potential PMRs to the PBAC (and/or its sub-committees)
- establishing a Review Reference Group (if requested by the PBAC/PBAC Executive)
- sourcing and managing contracts for research conducted by external parties

- facilitating the public consultation processes and Stakeholder forum (if required)
- drafting and editing the report to be presented to the PBAC and its sub-committees
- orchestration and management of sponsor PSCRs and pre-PBAC responses.

Evidence collation and evaluation

PMRs consider the most recent, relevant evidence available on the clinical safety, efficacy, and utilisation of the medicine/s of interest, as guided by the ToRs.

During the Public submission process of the PMR, stakeholders may provide input on the information and evidence to be considered as part of the Review. It is not necessary for all evidence to be in the same form as that provided as part of initial PBAC listing applications, although it must be robust and defensible. In particular, evidence on the safety and quality use of the medicine/s outside the clinical trial setting is valuable. Under ToR 5 (Consumer and First Nations considerations) consumers will also have the opportunity to provide input regarding their experience with the medicine(s) under review which may include information on efficacy, adverse events, and access issues.

Research for a PMR is typically contracted to independent external providers with demonstrated subject matter and technical expertise, selected from a panel of experts maintained by the Department. Most PMRs will involve a literature review and/or utilisation analysis. Additional evaluations may involve a systematic literature review, an economic analysis, further utilisation analysis, or other sources of evidence relevant to the Review.

Public submission process

A call for public submissions addressing the PMR is posted on the Post-market Review webpage and communicated via PBS News Update. Relevant sponsors and stakeholder groups will also be invited directly via email to provide a submission to the Review. All interested parties are welcome to make a submission to the Review. The standard submission period is a minimum of six weeks. This is an opportunity for stakeholders to identify additional areas for evaluation, particularly those issues related to how medicines are accessed and used by patients and their clinicians, and to comment on the research questions underneath each ToR. It also provides an opportunity to present any evidence or data that may inform the PMR, particularly evidence that the PBAC may not have previously considered.

All submissions received are published on the Post-market Review webpage at the conclusion of the public submission period, unless otherwise requested. Where submissions indicate commercial-in-confidence or sensitive personal information, this is redacted before publication.

All stakeholder submissions are made available to the PBAC (and its sub-committees) for consideration with the draft PMR report.

Stakeholder forum

Following the public submission process, a stakeholder forum may be held to offer interested parties an additional opportunity to provide input to the PMR. This would particularly be the case in Reviews that are of significant public/consumer interest or complexity.

Stakeholders will be given the opportunity to advise the Department about the need for and best timing of a stakeholder forum as part of the public consultation step on the PBAC-recommended PMR topic. The PBAC/PBAC Executive will take this stakeholder feedback into account when advising on whether a stakeholder forum should be held during approval of the Review ToRs. A stakeholder forum may not be warranted for all PMRs due to the size or scope of the Review, or because alternative consultation processes are considered more appropriate.

Forums will usually be held via webinar. Discussion is based on focus questions developed around the key points raised during the public submission process or evidence analyses. The forum is an opportunity for stakeholders to provide further comment on and to propose options to address these issues. The Department requires all participants of a stakeholder forum to declare any conflicts of interest (COIs) and to sign confidentiality agreements prior to attending the forum.

A summary of the forum is published on the Post-market Review webpage and included in the PMR report.

Reference Group

A Reference Group may be formed for a PMR to provide independent, expert advice on the draft report prior to consideration by the PBAC (and its sub-committees) if requested by the PBAC/PBAC Executive. A Reference Group may not be considered necessary if there is sufficient expertise in the membership of the PBAC and its sub-committees to guide the Review in terms of sources of evidence.

A Reference Group will be formed at the Department's discretion following a request received from the PBAC/PBAC Executive. If a Reference Group is formed for a Review, the timing for convening the Reference Group and the number of meetings held will be at the discretion of the Chair of the Reference Group.

Historically, Reference Groups have consisted of members who have expertise in HTA, drug utilisation, health economics, as well as consumer and stakeholder representatives. Reference Group members have also been selected for each PMR on the basis of demonstrated relevant expertise. Members of a Reference Group may also include:

- independent specialist clinicians and/or nurse practitioners

- researchers and representatives of peak healthcare professional organisations related to the medicine(s) under review
- health educators
- representatives of relevant consumer advocacy organisations
- representatives of industry groups.

The Department requires all Reference Group members to declare any COIs and to sign confidentiality agreements prior to joining the Reference Group. Information on the membership of the Reference Group for each PMR will be published on the Post-market Review webpage at the beginning of the Review and also included in the final PMR report.

Stakeholder consultation on the draft report

The draft report is provided to key stakeholders, including clinicians and consumer groups directly via email, and also made publicly available on the Post-market Review webpage for comment. The PMR Framework provides at least four weeks for stakeholders to submit up to four pages of comments and two pages of tables to the Department.

All stakeholder comments on the draft report are made available to the PBAC (and its sub-committees if applicable) for consideration alongside the draft PMR report. The draft report may also be revised based on stakeholder feedback where there is an error of fact identified during the consultation process and prior to consideration by the PBAC.

Sub-committee consideration of the draft report

The draft report will be provided to one or both sub-committees of the PBAC when it contains new evidence relevant to their area of expertise. Sponsors of the medicines included in the PMR will be provided with a copy of the draft report and given at least ten working days to provide a PSCR. The PSCR is limited to four pages of text and two pages of graphs and tables consistent with the initial PMR Framework and PBAC processes for assessing new submissions.

Following the sub-committee meetings, their advice to the PBAC will be provided to relevant sponsor companies to prepare a pre-PBAC response. Consistent with the initial PMR Framework, at least five working days are provided for sponsors to submit up to three pages of text, in response to the sub-committee advice, to the Department prior to the PBAC meeting. The draft report may also be revised to address certain sub-committee advice.

A PBAC sub-committee may request that additional information or analyses be provided, such as an economic evaluation. The sub-committee may request that the additional information is resubmitted to the same sub-committee for consideration at a later date, a different PBAC sub-committee, or provided directly to the PBAC.

Relevant sponsors will be provided with any additional information/analyses once completed and will be invited to submit a PSCR and/or a pre-PBAC response.

PBAC consideration of the draft report

The PBAC considers the draft PMR report, including stakeholder comments, sub-committee advice, sponsor pre-PBAC responses and any Reference Group comments (if applicable), before making recommendations.

In some cases, the PBAC may request additional work be conducted.

Sponsors of the medicine/s involved in the PMR are contacted after the PBAC meeting and provided with the minutes ahead of the PBAC meeting outcomes being published (six weeks post-meeting).

PBAC recommendations and options for implementation are provided to the Minister for consideration, where they impact on the PBS. The final PMR report and PBAC minutes are published on the Post-market Review webpage at the conclusion of the PMR.

The PBAC may make a range of recommendations based on its consideration of the PMR report, including:

- taking no action
- a change to PBS restrictions
- measures to ensure the ongoing cost-effective use of the medicine/s under review
- referral to relevant clinical organisations to update clinical guidelines
- education for health professionals or consumers to improve the quality use of the medicine/s under review
- a recommendation for a review of other related medicines or issues
- a request for additional information/analyses to be provided

Where the PBAC requests that additional information/analyses be provided to the committee (or a sub-committee) at a later date, relevant sponsors and stakeholders will be provided with the additional information once completed along with an invitation to submit a PSCR and/or pre-PBAC response.

Implementation of Recommendations

Recommendations relating to the PBS

Recommendations relating to the listing of the medicine/s under review are implemented according to standard post-PBAC processes. Under these processes, sponsors are advised of a recommendation following the PBAC meeting and will be followed up by relevant areas of the Department.

Other recommendations

Recommendations made by the PBAC that do not relate directly to the PBS will be referred on for implementation through existing, applicable programs, including through collaboration with state and territory health departments.

Recommendations to improve prescriber and/or clinical provider education may be implemented through relevant professional organisations or other areas of government.

Recommendations for changes to treatment or management guidelines may be implemented through the National Health and Medical Research Council (NHMRC) or in consultation with the external developer of the relevant guidelines.

Recommendations for future research may be referred to the area of the Department responsible for administering the Medical Research Future Fund for consideration in future grant rounds.

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All information in this publication is correct as of January 2024.