Australian Government
Department of Health, Disability and Ageing

Learn more about Post-market Reviews of medicines listed on the PBS

The term 'consumer' includes patients, carers, family members, consumer organisations and community members with experience of a health condition or medicine.

What is the PBS?

The Pharmaceutical Benefits Scheme (PBS) helps people access medicines at a lower cost. If a medicine is listed on the PBS, the government pays part of the cost.

What is a Post-Market Review?

A Post-Market Review (PMR) looks at how a medicine is being used after it has been listed on the PBS. It may look at one medicine or a group of medicines used for the same health condition.

A review may consider questions such as:

- who is using the medicine and how it is being used
- whether the medicine is working as expected
- whether there are safety concerns or side effects that need closer monitoring or support
- whether treatment guidelines or evidence have changed
- whether PBS rules or other information should be updated.

Each PMR is different. It looks at questions that are specific to that medicine or group of medicines.

A PMR is not a review of an individual person's treatment. If you are worried about your medicine, speak to your doctor, pharmacist or healthcare team.

More information about how PMRs are done is available in the Post-Market Review Framework.

Who decides that a PMR is needed?

The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent committee that advises the Minister for Health, Disability and Ageing about which medicines should be funded through the PBS. The PBAC can recommend a PMR:

- as a result of their consideration of submissions at their regular meetings
- because of issues raised by consumers, consumer organisations or other stakeholders

Before recommending a PMR, the PBAC may ask for a research project on the issue. The outcomes of the research (e.g. literature review or analysis of medicine use) inform consideration of potential PMR topics.

A PMR only proceeds after approval by the Minister.

Why do PMRs happen?

When a medicine is first listed on the PBS, the decision is based on the evidence available at the time. After listing, things can change. For example, new evidence may become available, treatment guidelines may change or the medicine may be used by more people or in different ways than expected.

A PMR helps the PBAC and the government understand whether any changes are needed to support the safe and appropriate use of the medicine.

What could happen after a PMR?

Each PMR is different. It may lead to no change, or changes such as:

- updated information for patients, carers, doctors or pharmacists
- changes to PBS rules, such as who can access the medicine through the PBS
- changes to the price that the government pays for a medicine through the PBS
- changes to how the medicine is monitored or reviewed in future
- further advice to government about the medicine or group of medicines.

Can consumers suggest a medicine or topic for review?

Consumers and other stakeholders can email PBSpostmarket@health.gov.au to suggest topics for future PMRs.

The PBAC considers the PMR workplan once or twice a year. Current reviews and research projects are published on the webpage.

How can consumers and consumer organisations share their views?

Consumers and consumer organisations can help by sharing what it is like to live with a health condition and use the medicine.

They can get involved by:

- checking PBAC meeting agendas and the PMR webpage for reviews that are underway
- subscribing to PBS News to hear about new reviews and feedback opportunities
- responding to public feedback opportunities through the Office of Health Technology Assessment Consultation Hub
- taking part if the department invites consumer organisations to provide a written submission or attend a stakeholder consultation meeting.

What kind of information is helpful?

The most helpful information explains why the issue matters to patients, carers or families. Examples of helpful consumer input include experiences of:

- how well the medicine or medicines work for the health condition
- whether the medicine is also being used for other health conditions
- side effects people may have had, including how serious they were, and how they were managed
- whether people need extra care, tests, hospital visits or support because of the medicine
- how the medicine affects quality of life, including mobility, independent living, return to work or school, caring responsibilities and family life
- whether the medicine is easy or difficult to access, including travel, time, costs, specialist appointments or hospital visits
- whether there are groups of people who may be affected differently, such as children, older people, rural or remote communities, Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse communities or people with disability,
- whether there are practical issues with taking medicine, such as injections, storage, monitoring, dose changes or interactions with other treatments.

Tips for writing consumer input

- use clear examples
- explain what changed before and after using the medicine, where possible
- describe both benefits and challenges
- say whether your comments are based on your own experience, your organisation's members, survey results or other sources,
- avoid including information that could identify a person unless they have agreed to it being shared.

What happens after consultation is closed?

Input from consumers is given to the PBAC to help inform its consideration of the review.

When a PMR is finished, the final review documents are published on the PBS website. These documents explain what the review looked at and the outcomes of the review.

Input from consumers and other stakeholders is usually published on the webpage for each PMR. If you do not want your input published, tell us when you provide it.

What this looks like in practice

A Post-Market Review looked at how people with severe plaque psoriasis used biologic medicines after the medicines were listed on the PBS.

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Severe plaque psoriasis is a long-term skin condition that can cause painful, itchy and inflamed patches of skin. It can also affect sleep, movement, relationships, work, study, and everyday activities. Biologic medicines work by targeting parts of the immune system that cause inflammation.

This PMR considered questions such as:

- are these medicines being used by the people most likely to benefit?
- has new clinical evidence changed what we know about these medicines?
- are the medicines providing good value for money?
- what are patients, clinicians and other stakeholders experiencing in real life?

Consumer input was collected through a Stakeholder Forum and a public consultation. This input helped the Review understand practical issues such as how psoriasis affects daily life, what treatments are likely to be used, and what matters most to people living with the condition.

This example shows how a PMR can bring together clinical evidence, medicine use data, healthcare professional advice and consumer experience to better understand whether PBS-listed medicines are being used the best way.

Where to find more information

- About the PBS | Pharmaceutical Benefits Scheme (PBS)
- Post-market Reviews of Pharmaceutical Benefits Scheme Subsidised Medicines | Pharmaceutical Benefits Scheme (PBS)
- Reviews | Pharmaceutical Benefits Scheme (PBS)
- Pharmaceutical Benefits Advisory Committee (PBAC) Membership | Pharmaceutical Benefits Scheme (PBS)
- PBAC Meeting Agenda | Pharmaceutical Benefits Scheme (PBS)
- Office of Health Technology - Citizen Space
- PBS Latest News | Pharmaceutical Benefits Scheme (PBS)

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