Update from the Pharmaceutical Benefits Advisory Committee

November 2024

The latest meeting of the Pharmaceutical Benefits Advisory Committee (PBAC) was held on 6 - 8 November. This update aims to enhance the Committee's communication to all stakeholders separate to the public summary documents, which will be published as usual.

Consumer and clinician input and involvement

A total of 59 submissions were received for the November 2024 meeting of which 38 required external evaluation by HTA service providers. Of these 22 submissions required complex economic evaluations (cost effectiveness/cost utility).

In relation to the submissions, the Committee received over 800 inputs, including over 500 inputs from individual patients, 120 comments provided by health care professionals, and 77 submissions from patient organisations. The Committee acknowledged the importance of these contributions and thanked those who contributed for their engagement and commitment to work with the PBAC to better support positive outcomes for patients.

Specific meetings to gain additional consumer and clinical input from groups prior to the November PBAC meeting included discussions with:

- Clinical experts on Dravet Syndrome
- Representatives of the migraine community as well as clinical experts
- Fibrodysplasia Ossificans Progressiva (FOP) Australia
- Clinical experts and industry regarding hormonal contraceptives

2025 agenda advice

For the March 2025 meeting, 63 submissions were received of which 51 required external evaluation by HTA service providers. Of these 38 submissions were for the most complex and resource-intensive type of submission. This type is where the sponsor has claimed that their medicine delivers better outcomes for patients than the current standard of care and requires a complex economic evaluation (cost effectiveness/cost utility).

The Department confirmed to the Committee that it had secured resourcing for 34 submissions to receive external evaluation in time for the March 2025 meeting and that it was securing additional evaluation resources for the remaining submissions to be considered at a special meeting of PBAC on Friday 9th and Saturday 10th May 2025. The members confirmed their availability and willingness to meet in May. The Committee noted that its deliberations about submissions to list medicines on the Pharmaceutical Benefits Scheme or vaccines on the National Immunisation Program designated vaccine determination requires that it is presented with a comprehensive evaluation of submissions, including input from the public through consultation, so that it can formulate advice to the Minister. The Committee reiterated that it expects that the department will provide the fully evaluated submissions, as well as clinical and patient inputs, to the Committee for all meetings, including both March and May 2025.

In relation to the considerations in March and May 2025, the Committee noted applicants were given an opportunity to provide further information about submissions they had proposed for March 2025. This further information was made available to all Committee members ahead of their discussions at the meeting.

The Committee then reviewed its advice from its out of session meeting on 16 October 2024 in light of the new information provided by the sponsors, and the final number and nature of submissions that had been lodged. In formulating its advice, the committee considered a balance of the following factors:

- the submission is for a medicine or vaccine which treats a patient population where there is high unmet clinical need or where the medicine is likely to provide substantial additional clinical benefit
- the submission is a resubmission lodged through the facilitated resolution pathway
- the submission is a codependent submission
- the corresponding TGA application to the submission received TGA priority determination
- the corresponding TGA application underwent the TGA provisional approval pathway
- the submission is for a medicine or vaccine which has received TGA orphan drug designation

On this basis the Committee then provided advice to the Department concerning those submissions which should be evaluated prior to consideration at the March 2025 meeting, and which should be evaluated prior to the May 2025 meeting. In formulating this advice, the Committee considered clinical need, potential patient benefit and the nature of the condition the medicines were intended to treat.

Medicine access considerations

The Committee agenda had several items which raised broader implications for PBS listings and current prescribing practice. The Committee was eager to ensure that listing restrictions and prescribing criteria support clinical groups and patients to access the most effective medicines on the PBS. The Committee noted that advances are occurring quickly in some therapeutic areas and ideally restrictions should support evolving clinical management and patient outcomes. The Committee engaged deeply in discussions relating to specific access issues for certain groups. Further information on these considerations will be found in the public summary documents.

Actions discussed by the Committee for further consultation with clinical and patient groups included:

- Appropriate access arrangements for paediatric populations living with conditions such as arthritis, Crohn's disease and other inflammatory conditions
- Opportunity to redress barriers in drug access for certain rare cancers because of gaps in clinical trial data
- Addressing access and equity constraints for particular high priority population groups. It was noted that these discussions will need broader policy considerations

Next PBAC meeting

The next PBAC meeting is an intracycle meeting on 13 December 2024. The next main PBAC meeting is scheduled for 12 – 14 March 2025. The agenda for the March meeting is now available and the opportunity for providing comments and input is open. The closing date for consumer comments is 29 January 2025.

Robyn Ward
Chair, Pharmaceutical Benefits Advisory Committee

Jo Watson
Deputy Chair, Pharmaceutical Benefits Advisory Committee