Update from the Pharmaceutical Benefits Advisory Committee

March 2025 Meeting

The latest meeting of the Pharmaceutical Benefits Advisory Committee (PBAC) was held 12th -14th March 2025. This update aims to enhance the Committee's communication to all stakeholders separate to the formal minutes of the meeting which will be published as usual.

Consumer and clinician input and involvement

A final total of 44 submissions were on the March 2025 meeting agenda, of which 32 required external evaluation. The submissions requiring external evaluations included 26 cost effectiveness/ cost utility analyses, and 4 cost minimization submissions.

In relation to the submissions, the Committee received over 1300 inputs, including 447 inputs from individual patients, 186 comments provided by health care professionals, 630 from parents and family / friends, and 69 submissions from patient organisations. The Committee acknowledged the importance of these contributions and thanks them all 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 PBAC meeting included discussions with:

- Clinical experts on Myasthenia Gravis, Neuroblastoma, and other cancer conditions
- Consultation with representatives of the PFIC patient community, and Myasthenia Alliance Australia

The Committee continues to note its concerns regarding the lack of transparency for consumer and clinical stakeholders of the relevant summary information for example, the details of which patients would receive the proposed medicine and the expected outcome of the use of the medicine under consideration. This results in a number of external inputs being received from engaged stakeholders that lack specific information or are not directed at the actual purpose of a sponsor submission. PBAC believes this is an unsatisfactory barrier for patients and clinicians and that sponsors should be reminded that this situation undermines the value of inputs being provided in relation to their submissions and the PBAC consideration of all the available evidence.

PBAC considerations

The PBAC meeting agenda had several items which raised Committee concerns about the lack of full information and materials for the Committee to be able to acquit its responsibilities under the relevant legislative requirements of the *National health Act 1953* (the Act). To ensure that PBAC can provide the most appropriate and considered advice to Government requires that Sponsor submissions provide meaningful evidence, data and effective price estimates to be able to be evaluated against the submission purpose and clinical and economic claims. The Committee notes that when such information is not provided or incomplete, then the outcomes of evaluations and Committee considerations will result in the sponsor needing to resubmit their proposals and additional material to future meetings. This leads to further resource impacts and unfortunate delays for clinicians and patients in the community as "submission churn" is driven by these deficits.

The Committee noted correspondence received from the Minister for Health and Aged Care, the Hon. Mark Butler MP, requesting that PBAC provide advice to the Australian Government on equitable access to medicines for treatment of obesity in Australia. The Committee discussed the broad aspects of this request and has asked the Department of Health and Aged Care to provide support for this work over the next months. The Committee also noted their intent to consult with relevant stakeholders during this period.

While considering a submission for the treatment of cervical cancer, the PBAC reflected that Australia aims to be the first country to eliminate cervical cancer by 2035, and was an "early adopter" for the national health system to implement both the National Cervical Screening Program and the listing of the HPV vaccine on the National Immunisation Program (NIP). Australia is progressing well toward the targets for screening, having already reached 70% coverage, and progressing well towards vaccination targets at 83%.

However, not all Australians have benefited equally from these interventions, especially for women in remote areas and young Aboriginal and Torres Strait Islander people. The PBAC recognized the need for medicines to treat cervical cancer, but it is disappointing that unless the Screening Program and HPV vaccinations reach their stated goals there will be women in Australia who will need treatment for a cancer that could have been prevented.

The PBAC noted that Australians with cancer have continued to access many newer and improved medicines in recent years. As a result of these improvement in treatment, life expectancy for some diseases has improved considerably, changing the treatment course for those conditions to be more aligned with long term or chronic conditions. When considering new medicines, the PBAC has reflected on the modest clinical benefits of some newer cancer medicines where there already exist a range of efficacious treatment options, while there remained opportunity for more improvements in outcomes for other patients with very high unmet needs where no drug development has occurred for a long time. The committee would like to note that it would welcome any future applications for drugs for these patient groups from relevant sponsors.

The PBAC emphasised the importance of ensuring access to medicines that relieve symptoms, even if an improvement to survival rates for patients has not been able to be realised. The committee were pleased to receive applications and supporting consumer and clinician comments on the importance of symptom relieving treatments for a number of conditions, and is committed to supporting meaningful quality of life improvements for patients when such submissions are available.

In some disease areas, many new medicines have become available through rapid research and development pathways. Not surprisingly, some current PBS restrictions on these medicines are not in line with evolving clinical guidelines and consensus statements when they become endorsed in Australia. The committee has emphasised again that it is committed to work with clinicians, sponsor companies, and consumers to update PBS restrictions to support best practice. This work will allow the PBAC to better position new medicines for the benefit of patients and to support their clinicians in delivering optimal clinical care in Australian settings.

Update from November 2024 meeting

To improve transparency in relation to the time taken to reach a PBAC recommendation we provide the following in relation to the November 2024 meeting. That meeting considered 34 new applications which required external evaluation, of these 13 had proceeded through the parallel pathway process and 21 did not. The latter applications are those for which the PBAC had received a positive TGA overview when the submission was lodged or the drug was already registered. The outcome for these applications is shown in the table below.

TGA application pathway	Recommended	Not recommended	Deferred
Parallel (n = 13)	12	1	
Not parallel (n=21)	17	3	1

Next PBAC meeting

The next PBAC meeting is scheduled for the 9th and 10th May 2025.

Robyn Ward
Chair, Pharmaceutical Benefits Advisory Committee

Jo Watson
Deputy Chair, Pharmaceutical Benefits Advisory Committee