



The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC25-002373

Ms Susan Templeman MP
Chair
Standing Committee on Petitions
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Dear Chair *Susan*

Thank you for your correspondence of 10 February 2025 regarding Petition EN6747 seeking to list Wegovy® (semaglutide) on the Pharmaceutical Benefits Scheme (PBS) for obesity.

The Australian Government is committed to ensuring Australians have access to affordable medicines by listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is an independent and expert body, comprising doctors, health professionals, health economists and consumer representatives. Under legislation, a medicine cannot be listed on the PBS unless the PBAC makes a recommendation in favour of listing.

When considering a medicine proposed for PBS listing, the PBAC is legally required to consider the comparative effectiveness and cost-effectiveness of the medicine compared to other available therapies. The PBAC's consideration is generally initiated when the pharmaceutical company responsible for a medicine applies for PBS listing for specific conditions. Pharmaceutical companies usually hold scientific data and other information necessary to inform the PBAC's consideration.

The PBAC has previously considered applications to list Wegovy on the PBS. At its March 2022 meeting, the PBAC did not recommend listing Wegovy on the PBS for obesity. The PBAC recognised the high burden of disease in Australia and welcomed input from a stakeholder forum held prior to the PBAC meeting. However, the application had poorly justified the eligible population, the modelled benefits were highly uncertain, and the listing was not considered cost-effective at the requested price. The PBAC considered that PBS listing of Wegovy would require an extremely high investment with very uncertain implications for the PBS and broader health budget.

At its November 2023 meeting, the PBAC considered a resubmission to list Wegovy on the PBS for the treatment of severe obesity despite prior participation in an appropriate lifestyle-based weight management intervention. The PBAC again did not recommend listing Wegovy on the PBS. The PBAC considered the resubmission did not provide a strong clinical rationale for the proposed PBS population and did not identify patients most likely to experience relatively large reductions in weight or long-term benefits from weight loss.

The PBAC acknowledged the high and urgent unmet clinical need for effective weight loss strategies for severe obesity, but considered that Wegovy was not cost-effective at the price proposed. The PBAC considered several issues remained outstanding, including that the resubmission had not provided new trial data on the cardiovascular benefits of Wegovy.

The PBAC considered that the value of this therapy is for patients at high cardiometabolic risk who are most likely to achieve long-term benefits from weight loss. The PBAC offered the sponsor a solution-focused workshop with one or more members of the PBAC, prior to it making a resubmission.

Further information about the PBAC's consideration and outcome is available in the Public Summary Documents (PSDs) for these items. The PSDs set out the specific detail of the PBAC's consideration, and are published on the PBS website at www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd, searching by product or meeting date.

A PBAC outcome does not necessarily represent the PBAC's final views on the merits of a medicine. The PBAC meets regularly and would consider further applications from Novo Nordisk Pharmaceuticals Pty Ltd concerning PBS listing of Wegovy for obesity. Pharmaceutical companies are private entities, and each company makes its own decisions about availability of its medicines, pricing of its medicines in the private market (outside the PBS), and whether it will apply for PBS listing. The Government cannot compel companies to submit applications.

On 6 March 2025, I wrote to the Chair of the PBAC to request that the PBAC provide advice to the Government on equitable access to medicines for the treatment of obesity in Australia. This may include, but not be limited to, the Australian population cohorts most likely to benefit from the potential future availability of Wegovy, or other anti-obesity medications such as tirzepatide, through the PBS. I also requested advice from the PBAC on the optimal duration of subsidisation, noting the limited long term safety data on the use of these medicines, and on whether these medicines are effective standalone therapies or best used in combination with other interventions, such as bariatric surgery or supporting models of care to achieve optimal patient outcomes.

The PBAC has previously recognised that equitable access to pharmacotherapy is only one aspect of the necessary public health response to obesity in Australia. The availability of consistent, standardised models of care and wraparound allied health services is essential. The advice that I have requested will assist sponsors in making future submissions to the PBAC for anti-obesity medicines and in PBAC's consideration of those submissions.

Thank you for writing on this matter.

Yours sincerely /

Mark Butler

19 / 03 / 2025