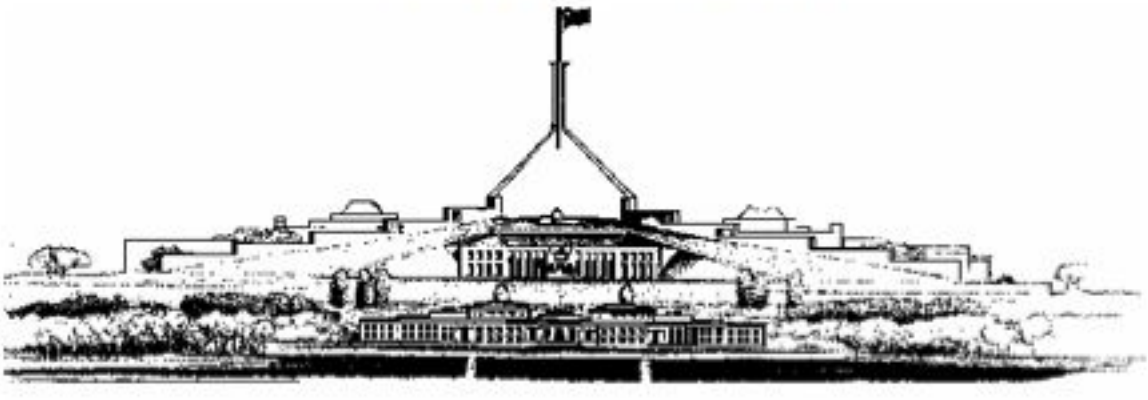
COMMONWEALTH OF AUSTRALIA

PARLIAMENTARY DEBATES



HOUSE OF REPRESENTATIVES

PROOF

PETITIONS

Medicinal Cannabis

PROCEDURAL TEXT

Monday, 10 February 2025

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES

PROCEDURAL TEXT

Date	Monday, 10 February 2025	**Source**	House
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Questioner		**Responder**	
Speaker		**Question No.**	

Medicinal Cannabis

Medicinal Cannabis

Dear Chair

Thank you for your correspondence of 3 November 2024 regarding petition number PN0624 on medicinal cannabis cost issues and access through the Pharmaceutical Benefits Scheme (PBS) for everyone that needs it.

I am aware many Australians are experiencing difficulties with the cost of medicinal cannabis, and that patients are reporting benefits since commencing treatment with the medicine. I acknowledge the challenges of each patient's experience and would like to thank you for sharing the petition.

The Australian Government enables 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, the Government can only list a medicine on the PBS when the PBAC recommends doing so. Similarly, the Government relies on the advice of the PBAC before changing an existing PBS listing.

When the PBAC evaluates applications for PBS subsidy, it is legally required to consider effectiveness and cost of the medicine, compared to alternative treatments. There is no legal provision for subsidised supply of a non-PBS-listed medicine, or for a PBS-listed medicine outside the terms of its listing (or specific restrictions). No exceptions are permitted for individual patients, even in particular cases where the medicine might be beneficial or recommended on clinical grounds.

Medicinal cannabis products are regulated medicines in Australia. Medicines are not generally made available on the PBS to treat conditions for which they have not been approved for use in Australia by the Therapeutic Goods Administration (TGA). This is important because the PBS listing process relies.in part on the assessment of quality, safety and efficacy that serves as the basis for TGA registration.

The TGA provides safe and legal access to medicinal cannabis in appropriate circumstances. Epidyolex(R) (cannabidiol) is registered by the TGA for seizures associated with Lennox Gastaut syndrome or Dravet syndrome and is PBS listed for these indications. Sativex(R) (nabiximols) is registered by the TGA for moderate to severe multiple sclerosis but is currently not listed on the PBS.

Sativex was considered by PBAC for PBS listing in 2013 and again in March 2020. The PBAC did not recommend listing at those times, due to limited evidence to demonstrate clinical efficacy and safety compared with standard treatment. Other than Sativex and Epidyolex, all other medicinal cannabis products are considered 'unapproved,' meaning they have not been evaluated by the TGA for safety, quality and efficacy.

The TGA encourages the use of medicines which have been approved in Australia and included in the Australian Register of Therapeutic Goods (ARTG). However, for various reasons, there are times when approved and available products may not meet the needs of all patients and clinical situations. In recognition of this, there are provisions that allow doctors and patients to access 'unapproved' treatments such as medicinal cannabis. These provisions include the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme.

Individuals are encouraged to speak to their treating doctor about the appropriateness of seeking access to 'unapproved' medicinal cannabis products for their individual circumstances. It is expected that the prescribing health practitioner will have considered all appropriate treatment options included on the ARTG and available in Australia, prior to considering accessing an unapproved good under the SAS or AP scheme for their patient(s).

The Government has no control over the price a supplier charges for 'unapproved' medicines. In some circumstances, a pharmaceutical company may be willing to supply its product at a reduced cost through a 'compassionate access' program. Decisions to grant access to such programs is one made by the company alone, and not by the Government. Individuals or their prescribing health practitioner may wish to contact the relevant company to enquire about the availability of such access programs.

Additionally, private health insurance subsidy of medicines is a matter for insurance companies. Some private health insurance providers may cover the cost of medicinal cannabis products. Individuals can contact their relevant health insurance provider for further information.

All aspects of patient care, including recommendations about appropriate treatments and interpretation of PBS eligibility and access, are the responsibility of the patient's treating doctor. I encourage patients to discuss information in this letter with their treating doctor.

Thank you for writing on this matter.

Yours sincerely

from the **Minister for Health and Aged Care, Mr Butler**