

Committee Secretary  
Senate Standing Committees on Community Affairs  
PO Box 6100  
Parliament House  
Canberra ACT 2600

[By email: [community.affairs.sen@aph.gov.au](mailto:community.affairs.sen@aph.gov.au)]

23 January 2020

Dear Secretary,

**ANZSPM submission: Inquiry into current barriers to patient access to medicinal cannabis in Australia**

The Australian and New Zealand Society of Palliative Medicine (ANZSPM) welcomes the opportunity to make a submission to the Senate Community Affairs References Committee (the Committee) regarding current barriers to patient access to medicinal cannabis in Australia.

ANZSPM is a specialty medical society representing practitioners of Palliative Medicine in Australia and New Zealand. Our members are medical practitioners who provide care for people with a life-limiting illness. Our membership currently includes more than 400 medical practitioners working in Australia.

While there is continued interest and ongoing research in the use of cannabinoids for symptom control, including in relation to palliative care patients, at present the evidence is uncertain and further research investment is required. ANZSPM is firmly of the view that the use of medicinal cannabis should be evidence-based and regulated in the same way as other prescribed medications.

We provide specific comments below, having regard to feedback from members, on the following terms of reference:

- a. the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA), Special Access Scheme, Authorised Prescriber Scheme and clinical trials;
- b. the suitability of the Pharmaceutical Benefits Scheme (PBS) for subsidising patient access to medicinal cannabis products;
- e. the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;
- g. sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened.

## **Appropriateness of the current regulatory regime**

- In a previous submission on the Medicinal Cannabis Bill 2014<sup>1</sup>, ANZSPM stated that the use of medicinal cannabis should be evidence-based, and that medicinal cannabis should be regulated in the same way as other prescribed medications. This view has not changed. ANZSPM believes that the use of medicinal cannabis should be under close medical supervision and supports access to medicinal cannabis through Special Access Scheme Category B (SAS-B), Authorised Prescriber, Clinical Trials or as a registered product. Such prescribing also needs to occur in the context of good assessment of palliative care issues and appropriate consideration of alternative therapeutic options which may have better efficacy and less harms in an individual situation. ANZSPM also notes that in some situations access to appropriate chronic pain or palliative medicine expertise, especially in rural or regional areas is hindering the access to such comprehensive assessment.
- Until there is evidence of efficacy and safety for specific cannabis products for particular indications, cannabis should remain unregistered by the TGA, and its prescription should require application for special access.
- There are different experiences among ANZSPM members with the SAS-B and Authorised Prescriber pathways, depending on what is more commonly used by local practices. However, broadly there seemed support for the current pathways, whichever is being used in practice. Specific feedback from members included:
  - The SAS-B pathway process is relatively straightforward, although it is recommended clinicians are familiar with cannabis products; know the indications, risks and benefits of cannabis; have developed a consent document; understand dosing; and have a plan for ongoing monitoring of efficacy and safety.
  - For some, the authorised prescriber scheme has proved to be less practical for a number of reasons. Firstly, palliative care patients are admitted across various campuses or hospitals during a single health-care episode and an authorised prescriber may be unable to attend the particular campus/hospital for ongoing prescribing/monitoring and this role cannot be delegated to junior staff. The clinical indications where the palliative medicine specialist may prescribe cannabis may include more than one indication (pain, nausea, anxiety, insomnia) and may not always be the same product/formulation.
  - For others, who only use the authorised prescriber scheme, the scheme has worked well, with prescribing only for patients enrolled on a clinical trial.
- State-based requirements, in addition to SAS approval, may also differ across the country and may present a minor additional burden for patients living close to border areas or where prescribing familiarity is less known.

## **Suitability of the PBS for subsidising patient access to medicinal cannabis products**

- For listing on the PBS, therapeutic goods must demonstrate not only efficacy and safety, but also cost-effectiveness. Until there is data for these measures for cannabis, it should not be listed on the PBS. For this to happen, pharmaceutical companies and governments need to invest substantially more money into high-quality clinical trials.

---

<sup>1</sup> <http://www.aph.gov.au/DocumentStore.ashx?id=c6693f2e-80e8-489c-8328-b8b54a870d45&subId=304713>

### Availability of training for doctors in the current TGA regulatory regime for prescribing

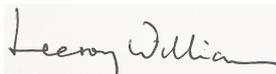
- There is limited training available for doctors. Most doctors do not have to interface the TGA special access pathways in their day-to-day work. The TGA guidance documents are helpful for prescribers, but do not address the specifics of the SAS-B pathway.
- ANZSPM also notes that medicinal cannabis is one therapy within a group of available pharmacological and non-pharmacological therapies for a given symptom or problem; and training needs to approach the assessment/treatment of the clinical problem as a whole; rather than silo information purely about cannabinoids.

### Sources of information for doctors about uses of medicinal cannabis

- The main barrier to prescribing of medicinal cannabis in the palliative care setting is lack of high-quality evidence to guide doctors. Doctors are reluctant to prescribe a medication for which generally they are unfamiliar with, and for which there is little high-quality evidence to guide them.
- Currently the best source of information for prescribing of cannabis is the information published by the TGA<sup>2</sup> - TGA guidance documents, analysis of all the available evidence for the use of cannabis for oncology (chemotherapy-induced nausea and vomiting) and palliative care indications undertaken by the National Drug and Alcohol Research Centre (NDARC) in 2017.
- However, these documents are guidance, not guidelines. They provide an indication of what symptoms have been addressed in trials, the adverse effects and strength of the evidence from those trials. In the case of palliative care indications, the strength of the evidence is weak. High-quality evidence is needed to produce clear guidelines addressing how to prescribe, what product to choose, how to titrate doses etc.
- Evidence from high-quality clinical trials is the best source of information for prescribing. A number of ANZSPM members are internationally renowned in research, with considerable experience and involvement in conducting high-quality clinical trials in palliative care.
- Further investment in research will improve the strength of evidence for the efficacy and safety of medicinal cannabis for palliative care (and oncology) patients. Investment directed towards pre-clinical research leading to clinical trials work and access to a broad range of products with preclinical data could accelerate understanding of the therapeutic use.

We welcome further participation in this inquiry and look forward to the Committee's findings.

Yours sincerely,



A/Prof Leeroy William  
President



Simone Carton  
Chief Executive Officer

---

<sup>2</sup> <https://www.tga.gov.au/medicinal-cannabis-guidance-documents>