Current barriers to patient access to medicinal cannabis in Australia

Clinical Oncology Society of Australia

Submission to the Senate Standing Committees on Community Affairs

Current barriers to patient access to medicinal cannabis

Thank you for the opportunity to make a submission to this inquiry.

The Clinical Oncology Society of Australia (COSA) is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients. Our vision is that all Australians receive quality multidisciplinary cancer care from supported and informed health professionals who work in a multidisciplinary manner.

Summary

- COSA supports the consistent application of existing regulatory pathways to all therapeutic products accessed in Australia.
- COSA supports the existing pathways to access non-TGA approved products and the use of these pathways for any non-TGA approved product.
- COSA strongly recommends reporting of the indication, safety, quality and other outcomes of interest, of non-TGA approved medicinal cannabis-based therapeutic products prescribed through either the Special Access Scheme or an Authorised Prescriber to enable the collection of real-world data to inform future availability and use of medicinal cannabis.
- COSA supports the use of the Pharmaceutical Benefits Scheme for subsiding patient access to medicinal cannabis products.
- COSA members welcome clarity about the legal implications for people using medicinal cannabis prescribed through appropriate pathways while driving a vehicle.
- In summary, we reiterate our position on the matter of medicinal cannabis as outlined in our joint position statement with Cancer Council which can be found by reading the COSA and Cancer Council position statement on medicinal cannabis and cancer.[8]

Terms of reference

We have addressed the terms of reference below.

(a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access, Scheme (SAS), Authorised Prescriber Scheme and clinical trials;

In Australia, medicinal cannabis refers to a range of quality assured, pharmaceutical cannabis preparations, for the relief of a medical condition and must be prescribed by a doctor. [1-2] It should be taken as prescribed. Unregulated cannabis contains unknown concentrations of cannabinoids and may expose patients to harmful pesticides, fungicides and bacteria. Community interest must be met with appropriate clinical evidence, best practice guidance and safety frameworks.

COSA supports the consistent application of existing regulatory pathways to all therapeutic products accessed in Australia. The Therapeutic Goods Administration's (TGA) review of safety, quality and efficacy are critical to ensure therapeutic products accessible to prescribers and their patients will likely produce the intended effect with limited harm. Medicinal cannabis products must undergo the same regulatory assessment and compliance as all other therapeutic products. It is also important to understand that evidence of effectiveness in one indication does not necessarily translate to other indications.

COSA supports the existing pathways to access non-TGA approved products and the use of these pathways for any non-TGA approved product. The Special Access Scheme and Authorised Prescriber program enables the TGA to review either individual cases for access to non-TGA approved products or monitor prescribers granted authority which ensures safeguards are in place for appropriate and controlled use for people who may benefit from using a non-approved product. However, the variable availability of medicinal cannabis products within the current schemes is problematic as it is currently impossible to compare different formulations and their effects when substitution is required. This can result in reduced clinical effect or adverse events.

COSA strongly recommends reporting of the indication, safety, quality and other outcomes of interest, of non-TGA approved medicinal cannabis-based therapeutic products prescribed through either the Special Access Scheme or an Authorised Prescriber to enable the collection of real-world data to inform future availability and use of medicinal cannabis.

Clinical trials offer cancer patients additional treatment options and quality care. There are currently several clinical trials underway at various phases to investigate the use of medicinal cannabis in advanced cancer. COSA is interested in the outcomes of these trials. These trials are investigating efficacy and safety in advanced cancer patients with the aim of relieving pain, increasing appetite and reducing chemotherapy-induced nausea and vomiting, and effect on tumour growth. This provides patients with early access to a potentially effective option when conventional options have been unsuccessful. Clinical trials are important in determining the safety and efficacy of a product and determining prescribing advice in a specific indication.

(b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;

COSA supports the use of the Pharmaceutical Benefits Scheme for subsiding patient access to medicinal cannabis products. COSA does not believe it would be appropriate to separate medicinal cannabis products from the existing cost-effective assessment or subsidy arrangements required for all therapeutic products.

(c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;

COSA does not have the information to provide a comment.

(d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;

COSA does not have the information to provide a comment.

(e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;

There are currently no cannabis and cannabinoids, natural or synthetic, based therapeutic products listed on the Australian Register of Therapeutic Goods indicated for use in cancer care in Australia. The TGA approves recommendations for prescribing when a product is registered. As there are currently no medicinal cannabis products registered on the Australia Register of Therapeutic Goods for a cancer indication, prescribing guidelines are unavailable. Without this, it can be difficult for doctors to prescribe and understand the potential effects the product may have on the patient, and interactions with other medicines. In the absence of prescribing guidelines, the TGA developed a set of guidances for doctors wishing to prescribe unapproved cannabis products. COSA directs enquiries about medicinal cannabis and cancer to these documents.

Currently there are no formal international or national supportive care guidelines for prescribing cannabis for the effective management of side effects of cancer or cancer treatment. Medicinal cannabis is not a recommended treatment option in the Multinational Association for Supportive Care in Cancer (MASCC) and European Society for Medical Oncology (ESMO) consensus Guidelines on the Prevention of Chemotherapy and Radiotherapy Induced Nausea and Vomiting,[3] or the Australian eviQ clinical resources for the Prevention of chemotherapy induced nausea and vomiting,[4] and Management of radiotherapy induced nausea and vomiting.[5]

Doctors express the need and interest in more education and information about medicines, particularly cannabis where education is limited. It is unclear whether the current remit of the TGA includes providing specific training for doctors. The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. The TGA does not give clinical advice regarding medicines, health products or treatments. Without approved products available, it is difficult to suggest who should provide training for unapproved products and where the responsibility lies for the provision of prescribing guidelines.

(f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;

Education is addressed in Terms of Reference (e).

(g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;

For support doctors who wish to prescribe non-approved cannabis-based therapeutic products, the TGA released a set of clinical guidance documents across a range of conditions to support informed decision making with their patients.[6] These guidance documents provide advice on the use of medicinal cannabis in the treatment of palliative care patients in Australia, and for the prevention or management of nausea and vomiting in Australia. In addition, the Australian Centre for Cannabinoid Clinical and Research Excellence have developed NSW Cannabis Medicines Prescribing Guidance 'to provide interim information to support NSW medical practitioners in prescribing cannabis medicines to patients for conditions where cannabinoids are perceived to have some benefit '.[7]

(h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;

COSA does not have the information to provide a comment.

(i) the current status of the domestic regulated medicinal cannabis industry;

COSA does not have the information to provide a comment.

(j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;

COSA does not have the information to provide a comment.

(k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;

COSA does not have the information to provide a comment at the time of submission however, COSA members work in rural and remote areas and could advise on this area if the Committee would like further advice.

(l) the significant financial barriers to accessing medicinal cannabis treatment;

COSA does not have the information to provide a comment.

(m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that; and

COSA does not have the information to provide a comment.

(n) any related matters.

COSA members welcome clarity about the legal implications for people using medicinal cannabis prescribed through appropriate pathways while driving a vehicle. Australian police conduct random roadside drug tests which detect the presence of cannabis. To our knowledge this cannot currently differentiate between prescribed medicinal cannabis and cannabis used recreationally, which remains illegal. This is a concern for prescribers and their patients using medicinal cannabis, and it has also been identified as a barrier to clinical trials participation as many patients want to maintain as much of their usual life as possible, which can include driving. This is also a public concern to ensure medicinal prescriptions do not interfere with ability to drive.

Further information and evidence on medicinal cannabis and cancer can be found by reading the COSA and Cancer Council position statement on medicinal cannabis and cancer.[8]

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