Australian Government
Department of Health and Aged Care

Deputy Secretary

Dr Nick Yim
President
Australian Medical Association (AMA) Queensland

Professor Brett Emmerson
Chair, Queensland Branch
The Royal Australian and New Zealand College of Psychiatrists

Chris Owen
President
The Pharmacy Guild of Australia, Queensland

Dear Dr Yim, Professor Emmerson and Mr Owen,

Thank you for your correspondence of 21 November 2024 concerning the high-volume prescribing of unregistered medicinal cannabis products in Queensland.

The issue of medicinal cannabis patient access is a priority matter for the Therapeutic Goods Administration (TGA). As you have noted in your correspondence, over the past few years there has been a steep increase in applications for unregistered medicinal cannabis products under the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme, particularly for products within Category 5 (THC ≥98%). This increase in prescribing of medicinal cannabis medicines is coupled with the emergence of single-medicine online models of care, whereby consumers access a service for the purpose of obtaining a particular medicine (such as medicinal cannabis or weight-loss medicines).

As you are aware, in March 2024 the Department of Health and Aged Care established the Medicinal Cannabis Expert Working Group (MCEWG). In collaboration with the MCEWG, we are exploring mechanisms by which regulatory safety risk controls can be integrated into the current patient access framework to ensure patient safety. As part of usual Government process, consultation is generally undertaken prior to any amendment to policy or legislation. Before any change is made to policy or law the TGA will consult with a wide range of stakeholders,

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including peak representative bodies for medical, pharmacy and industry and consumer groups.

We have also been working collaboratively with health regulators in Australia to better understand the online prescribing landscape and areas requiring further strengthening, with an agreement to work collaboratively in addressing these concerns.

I acknowledge the importance of timely access to unregistered therapeutic goods to address the medical needs of patients, in clinical circumstances where there are limited or no approved treatment options. The prescribing of an unregistered medicinal cannabis product through the SAS, as with any unregistered therapeutic good, requires the prescribing clinician to comply with good medical practice, the principles that characterise ethical and professional conduct expected of doctors by their professional peers and the community.

The TGA does not regulate the clinical practice of individual health practitioners. However, I note that the Australian Health Practitioner Regulation Agency (Ahpra) has recently established a Rapid Regulatory Response Unit to proactively investigate matters where a formal complaint (notification) has not been received but where there is some evidence of harm and/or non-compliance. I understand medicinal cannabis is a priority area for the Unit, and the TGA is actively supporting this work.

Regarding the provision of clinical guidance for medical practitioners, it is important to note that the development of clinical guidance is generally outside the remit of the TGA. It would be highly valuable for best practice clinical resources to be led by expert peak medical and pharmacy bodies with the relevant expertise in conditions where medicinal cannabis is being prescribed in high volumes, such as for the management of chronic pain and anxiety. This would include the relevant medical colleges.

If you have any further questions, please do not hesitate to contact the Chief Medical Adviser and Chair of the MCEWG, Professor Robyn Langham, via email at [redacted].

I look forward to a continuing collaborative relationship.

Yours sincerely

[redacted]

Professor Anthony Lawler
Health Products Regulation Group

29 November 2024