A Provisional Evaluation of Australia's Medical Cannabis Framework

Myfanwy Graham[1,2], Vivian Chiu[3], Daniel Stjepanović[3], Wayne Hall[3]

[1]Monash Addiction Research Centre, Monash University, Melbourne, Australia, [2]Shaeffer Center for Health Policy & Economics, University of Southern California, Los Angeles, Australia, [3]National Centre for Research on Youth Substance Use Research, University of Queensland, Brisbane, Australia.

Presenter's email: Myfanwy.graham@monash.edu.au

Introduction: Prescribed medical cannabis was legalised in Australia in 2016. This study assesses how well the Australian program has addressed the challenges of providing patients with easier access to medical cannabis while ensuring that high-quality products are used safely and effectively under medical guidance.

Objectives: 1.) Describe prescribing approval patterns and product availability; 2.) Describe adverse events with prescribed medical cannabis.

Methods: Policy framework transitions were evaluated against a defined set of policy goals [1]. A descriptive analysis of the federal medicines regulator prescription approval data, product availability, externally facing Database of Adverse Event Notification (up to 14/07/2023), and internal adverse event report data (up to 21/03/2023) was completed using SAS (version 9.4) [2-3].

Results: Despite broadening access over time and almost universal regulatory approval of applications to prescribe (98%), most patients using cannabis with medicinal intent, access it outside of the legal framework. Within the medical framework, more recent prescribing approval trends, particularly for psychiatric indications are not consistent with prescribing guidance. A diverse range of medical-grade products are available, although some prescription products available for inhalation have higher delta-9-tetrahydrocannabinol potency (>30%) than would be anticipated for a medical market and are in the potency ranges seen in recreational markets. To our knowledge, this study is the first comprehensive analysis of adverse events reported to the federal medicines regulator. The 1297 adverse events reported in the 549 unique reports are stratified by age, sex, and cannabinoid.

Conclusions: Medical program evaluation findings related to access outside legal pathways, recreational product potency, prescription patterns, and potential harms provide critical insights to inform future policy decisions.

Disclosure of Interest Statement: MG was supported by an NHMRC Postgraduate Scholarship and Monash Graduate Excellence Scholarship (APP2030765).

References

1.) Belackova V, Shanahan M, Ritter A. Mapping regulatory models for medicinal cannabis: a matrix of options. Aust Health Rev. 2018 Aug;42(4):403-411.
2.) Therapeutic Goods Administration. FOI 1741 document 1 request for documents relating to adverse event reports for medicinal cannabis products. FOI disclosure log (2020). Available from https://www.tga.gov.au/sites/default/files/foi-1741-01.pdf
3.) Therapeutic Goods Administration. FOI 3981 document 1 data from adverse event reports for the period 25 May 2020 to 15 September 2022, for medicines containing cannabinoids. FOI disclosure log (2022). Available from https://www.tga.gov.au/sites/default/files/2022-10/foi-3981-01.pdf

4.) Therapeutic Goods Administration. FOI 4297 document 1 medicinal cannabis – special access scheme and authorised prescriber data. FOI disclosure log (2023). Available from https://www.tga.gov.au/sites/default/files/2023-04/foi-4297-02.pdf