

# A provisional evaluation of Australia's medical cannabis program – Adverse events

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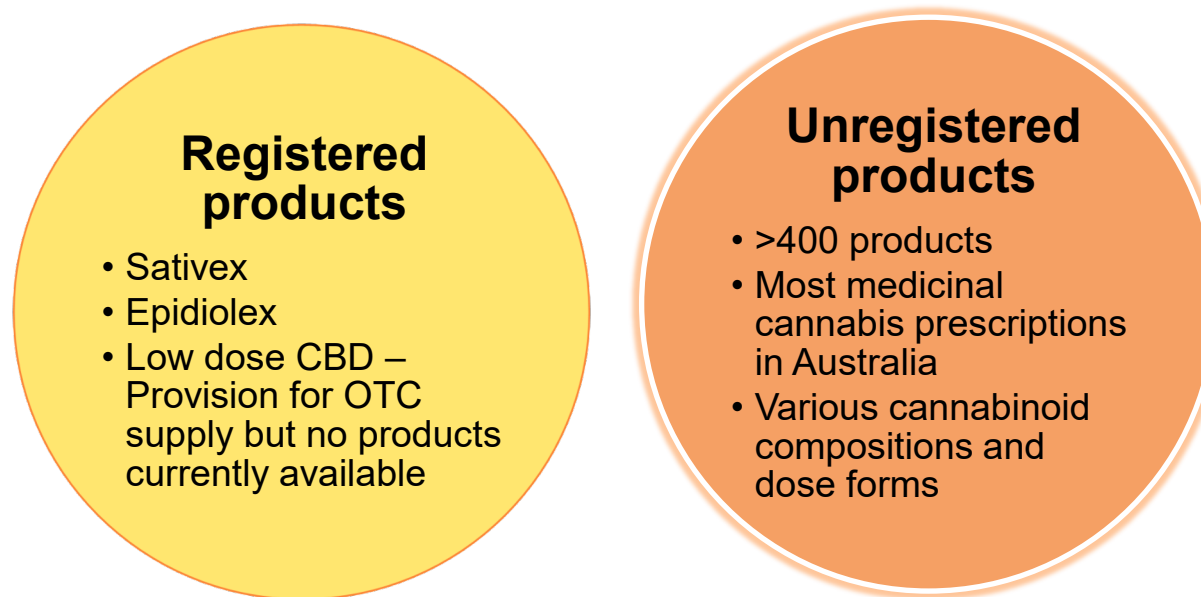
# Disclosures

I declare that I have received funding from:

- Australian Government, Department of Health and Aged Care
- National Health and Medical Research Council
- Monash University
- World Health Organization
- University of Southern California
- Australian-American Fulbright Commission (Australian and U.S. governments)
- University of Newcastle
- NSW Health's Clinical Cannabis Medicines Program

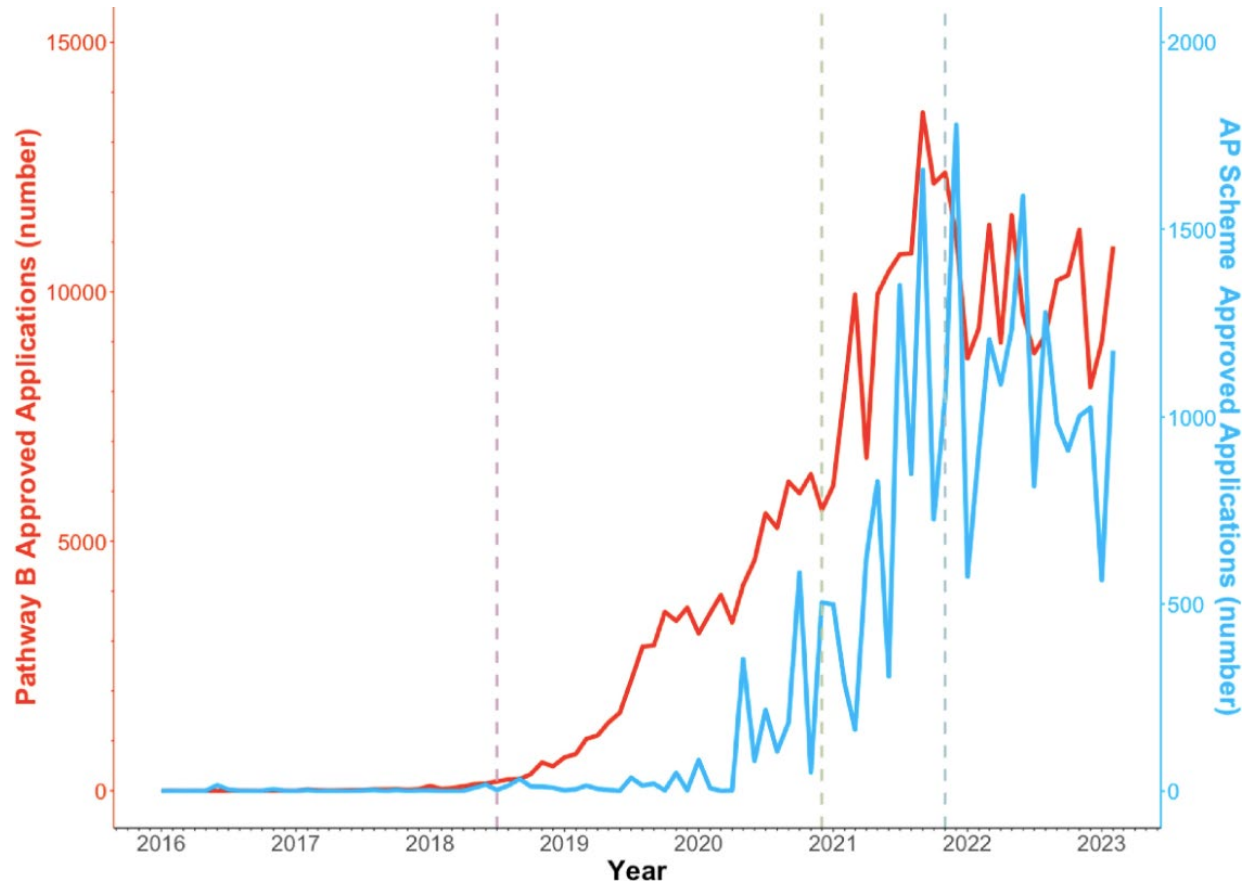
# Background

- Prescribed medicinal cannabis (e.g. delta-9-tetrahydrocannabinol) available since 2016
- **Medicalized model** – medical doctors and nurse practitioners prescribe



The presentation will focus on voluntary adverse event reports related to unregistered medicinal cannabis to the federal medicine regulator the Therapeutic Goods Administration.

# TGA Prescription approvals

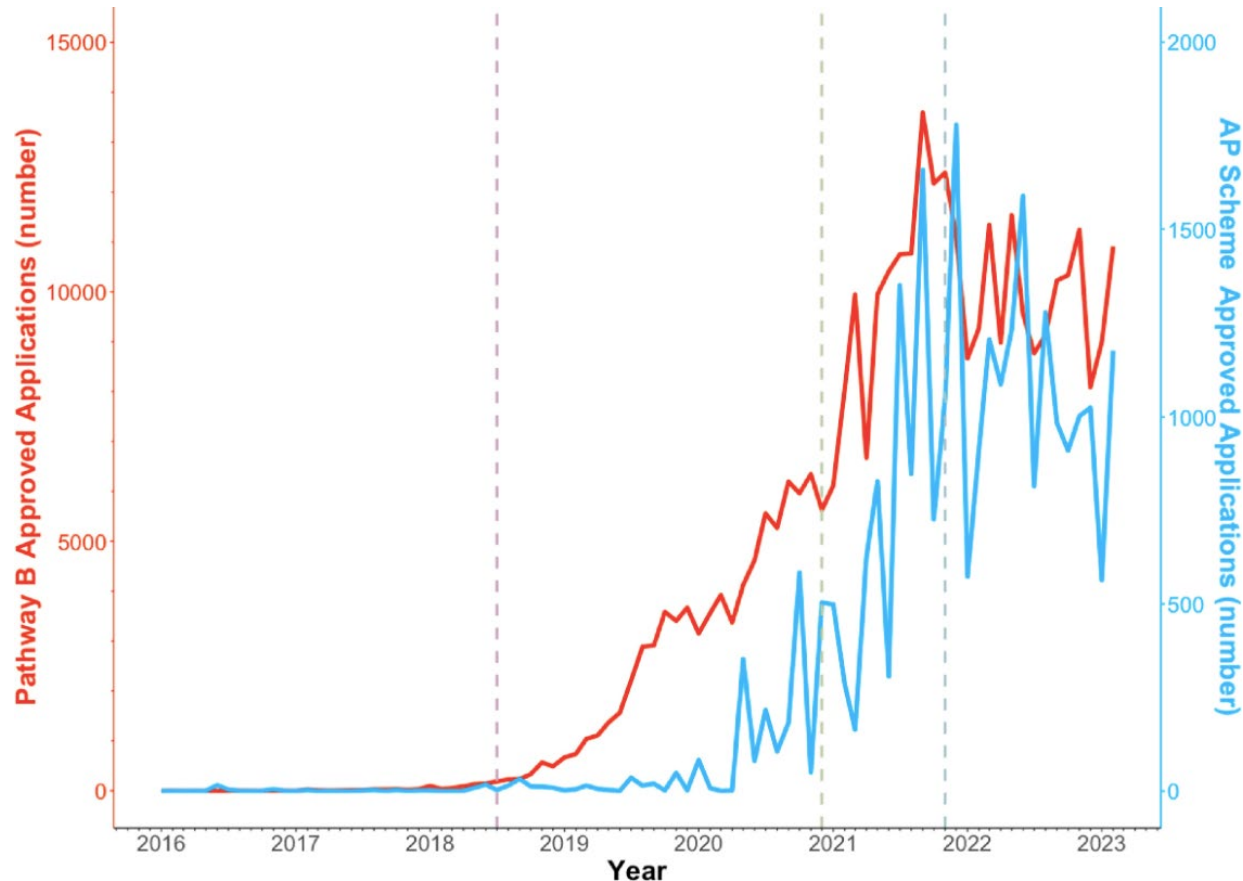


Prescribers apply to the TGA for approval to prescribe medicinal cannabis via SAS or AP pathways

- **July 2023** 385,163 SAS-B approvals and 5084 prescribers  
31,190 AP applications and 2100 prescribers
- **October 2024** 587,702 SAS-B approvals and 5996 prescribers  
56,857 AP applications and 2993 prescribers

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# TGA Prescription approvals



**Pivotal federal regulatory shifts** (dashed lines), including:

- online application portal (July 2018)
- low dose CBD announcement (December 2020)
- change to AP pathway and medical cannabis category based approvals (November 2021).

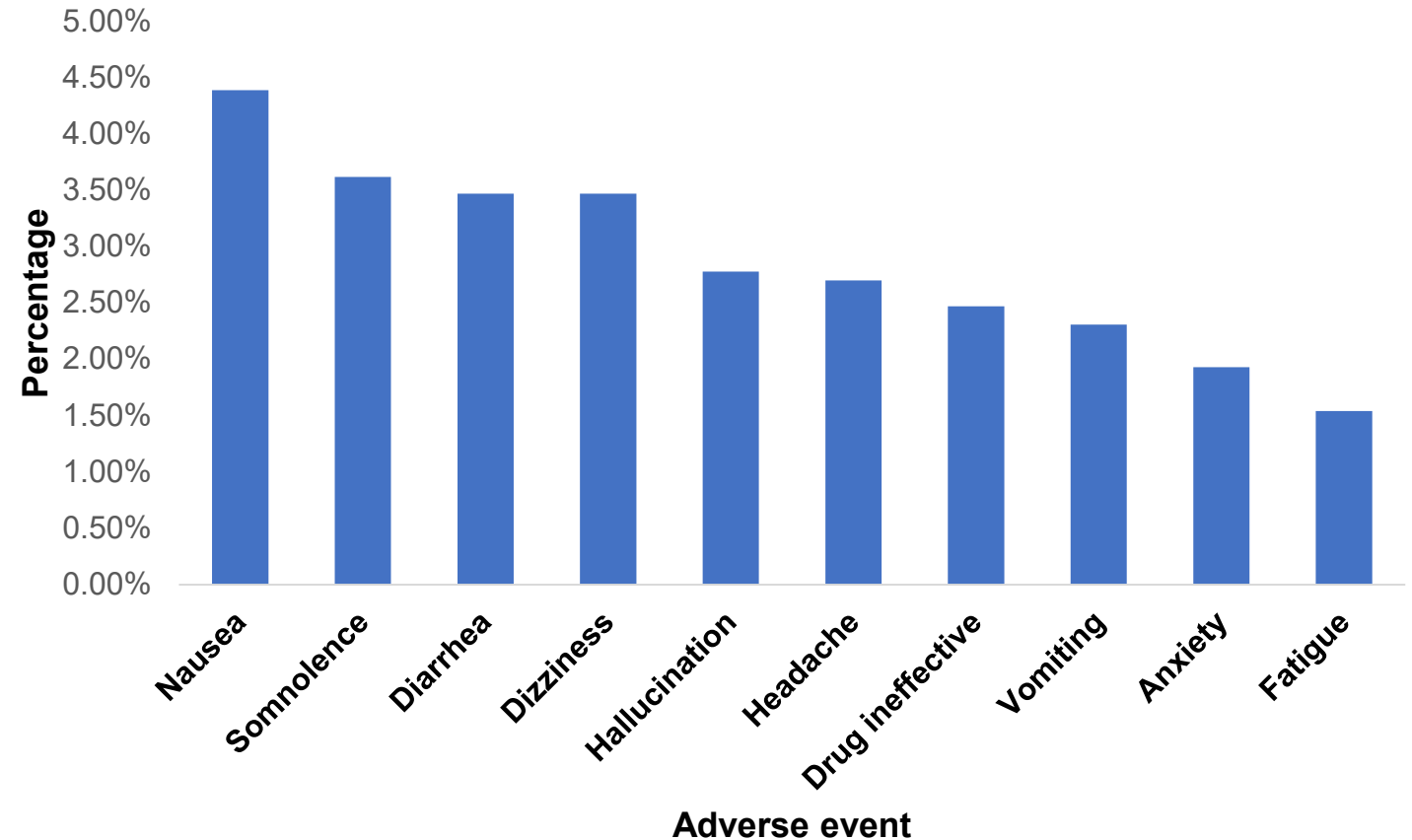
In parallel, increased prescribing via **cannabis clinics (e.g. telehealth)**

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# Prescribed medical cannabis – Adverse events

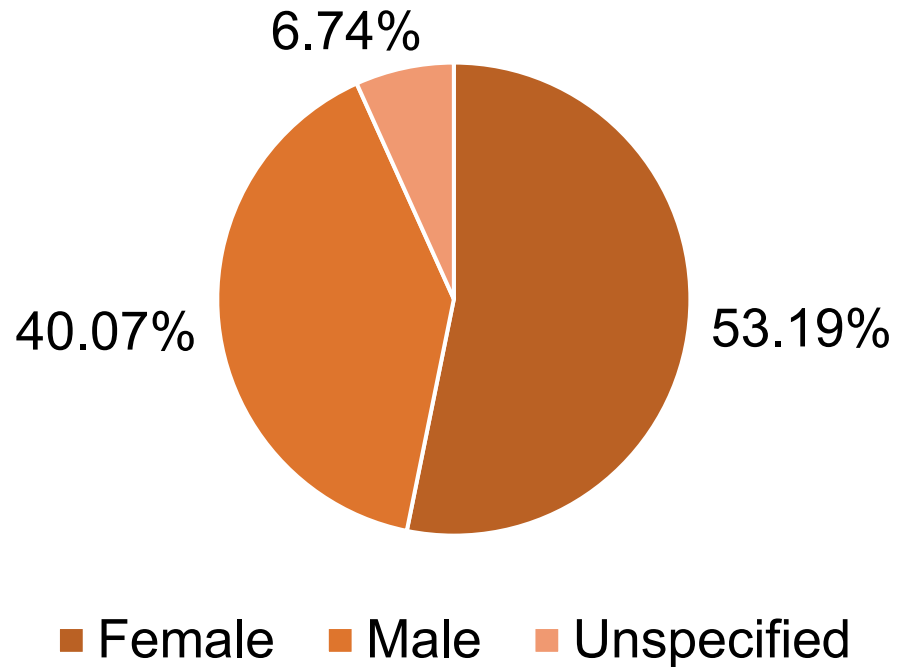
- Internal AE data was obtained via a freedom of information (FOI) request.
- Reports to the TGA 29/09/2016 to 21/03/2023\*
- **1297 AE were reported in 549 unique reports**

**Nervous system, psychiatric and gastrointestinal** adverse events reported here are consistent with international AE data



\*and DAEN data up to 14/07/2023. Graham et al. 2023 IJDP

# Adverse events – Demographics and products



Less than 18 years old 17.26%  
Greater than 65 years old 26.19%



CBD+THC 59.02%



CBD only 39.53%



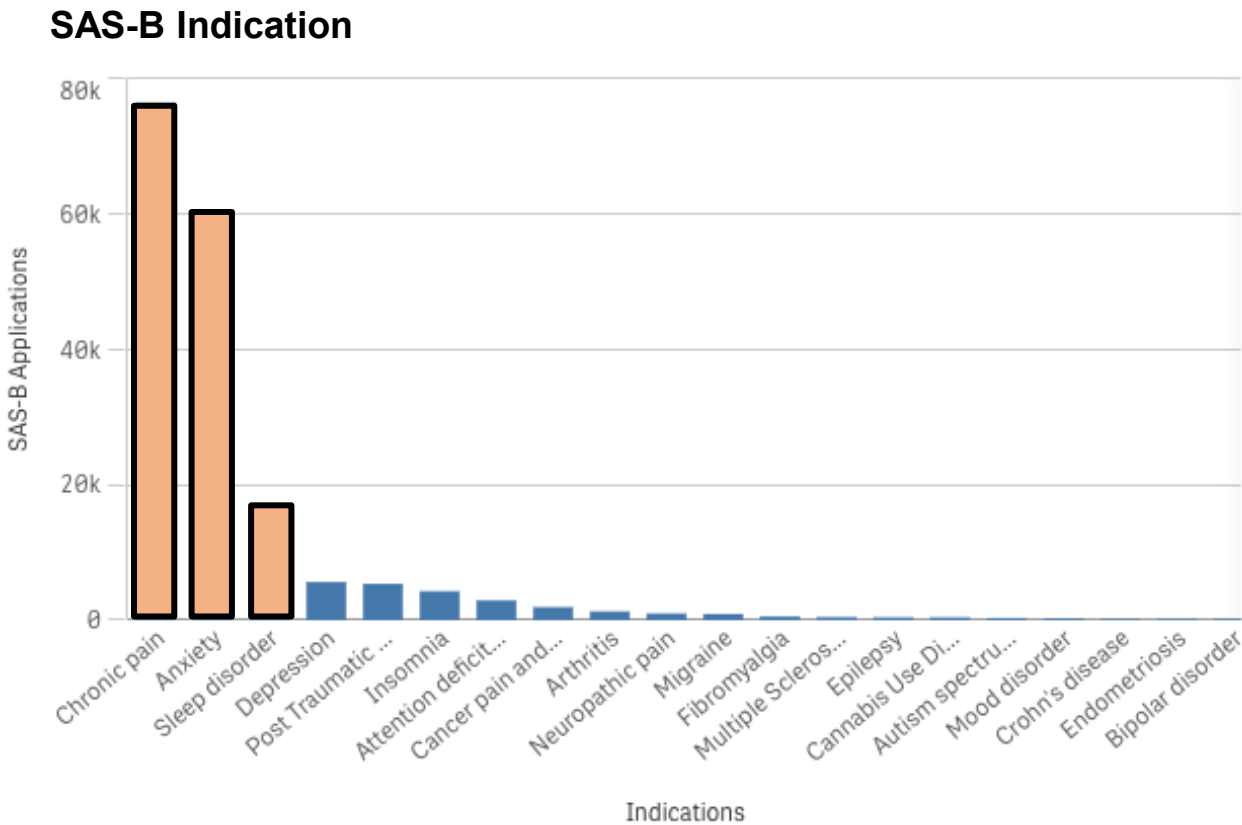
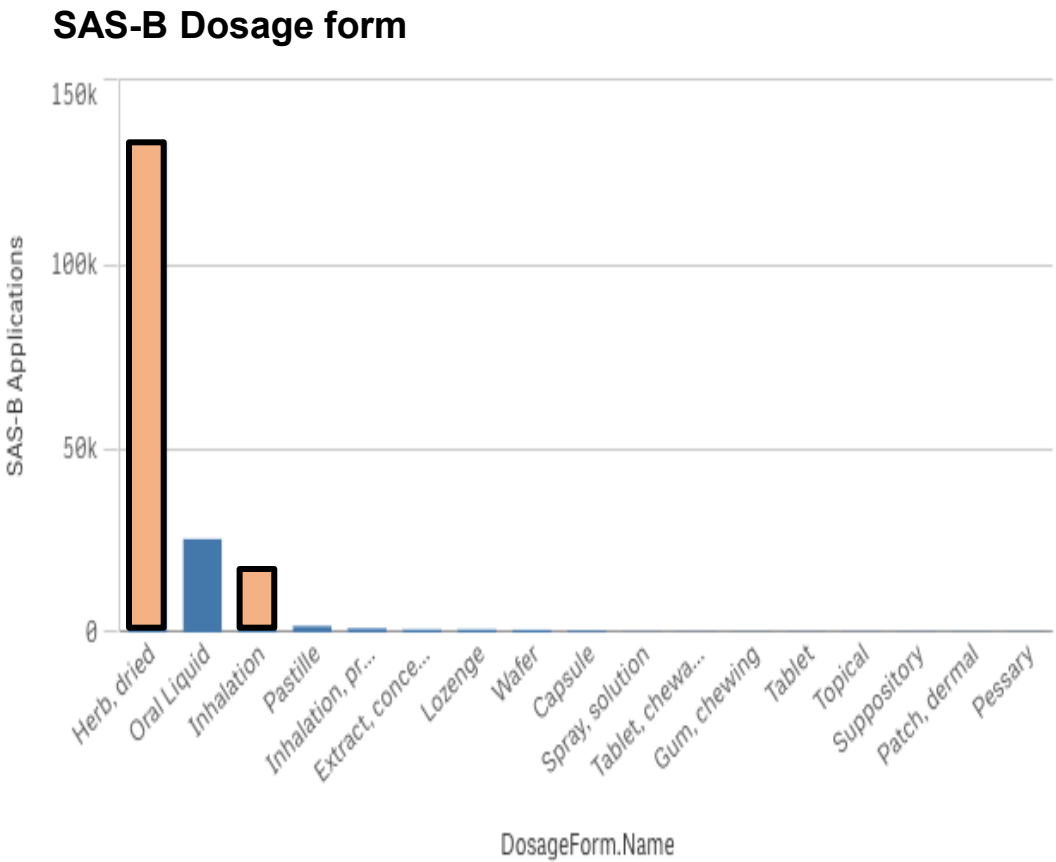
THC only 1.46%



**Cannabinoid-drug interactions 37.7% (n = 207/549)**

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# Shift in prescribing patterns – Oil to inhaled products



TGA SAS-B dashboard 24<sup>th</sup> Oct 2024



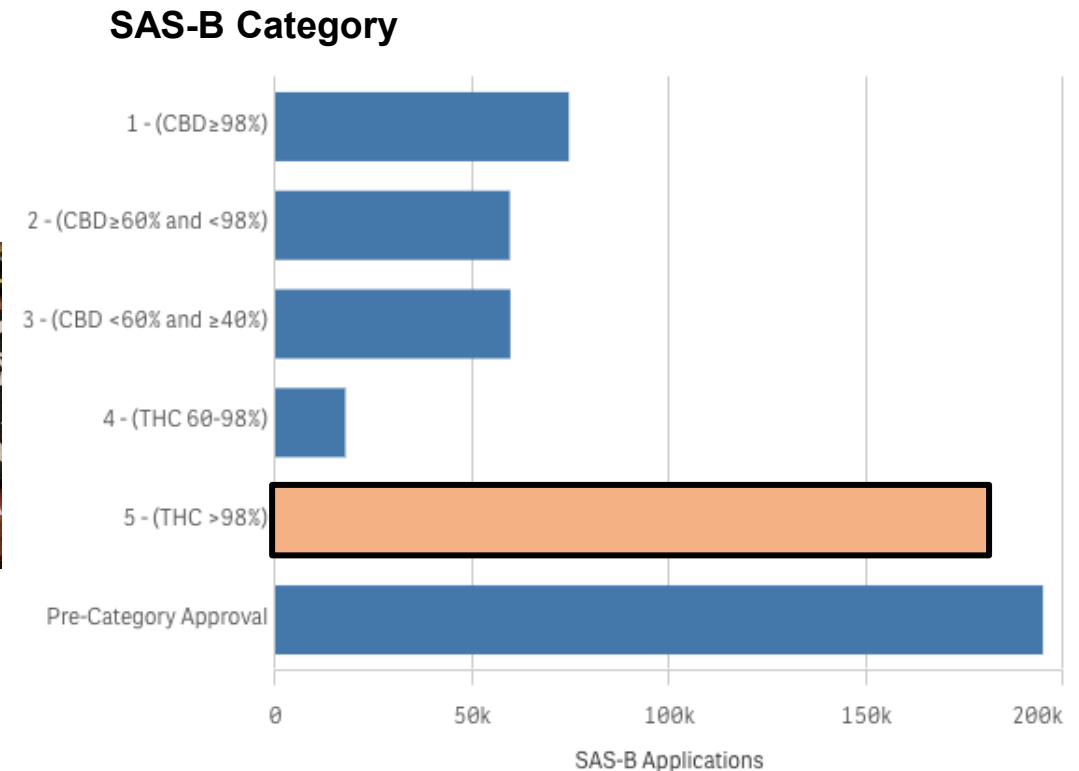
# High-potency THC products in a medical market

Some prescription products available for inhalation have **higher THC potency** than would be anticipated for a medical market and are in the potency ranges seen in recreational markets.

- Extracts up to 88%
- Flower up to 60% (biological limit ~35%)
- Inhalation up to 880 mg/mL and 85%
- Oral liquid 20 mg/mL to 50 mg/mL



Between Sep 2022 to Oct 2023, **>60% of the prescription approvals** for anxiety were **Category 5 THC dried herb and inhalation products**.



TGA SAS-B dashboard 24<sup>th</sup> Oct 2024

# Conclusions

- Following the shift in prescribing approval patterns towards higher THC potency inhaled products, it will be critical to track adverse event trends using a variety of data sources.
- Although the proportion of the population accessing regulated prescribed medicinal cannabis in Australia has increased over time, it is still less than the proportion that access cannabis outside of regulated pathways.
- Therefore, **comprehensive cannabis pharmacovigilance frameworks** are essential to provide more detailed insights into its safety profile and health outcomes.



# Thank you

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QR code for the full paper in IJDP

## Collaborator Acknowledgement:

- Vivian Chiu
- Daniel Stjepanović
- Wayne Hall

# Cross-National Survey of Clinical Decision-Making About Medical Cannabis Products (New York State, United States; Australia)

**This study seeks to improve understanding of cross-national health professional and non-health professional practices and information needs related to medical cannabis products.**



This research is open to all persons aged 21 years or older who consent to participate and are currently registered medical practitioners in Australia.

You will have the opportunity for compensation for your time and expertise.

For further information, please visit the study [webpage](#) or contact the study team directly at [clincan.study@monash.edu](mailto:clincan.study@monash.edu)



University of Newcastle HREC Approval No. H-2023-0199; University of Southern California IRB Approval No. UP-23-01039.