Session 4

Discussions and updates on TGA activity in the medicinal cannabis space

Moderator: Clare Barker, Industry Expert

Presenters: Chris Bedford, HPRG
Prof Robyn Langham, TGA
Avi Rebera, ODC

In conversation with the Australian regulators

Chris Bedford

Acting First Assistant Secretary,

Health Products Regulation Group

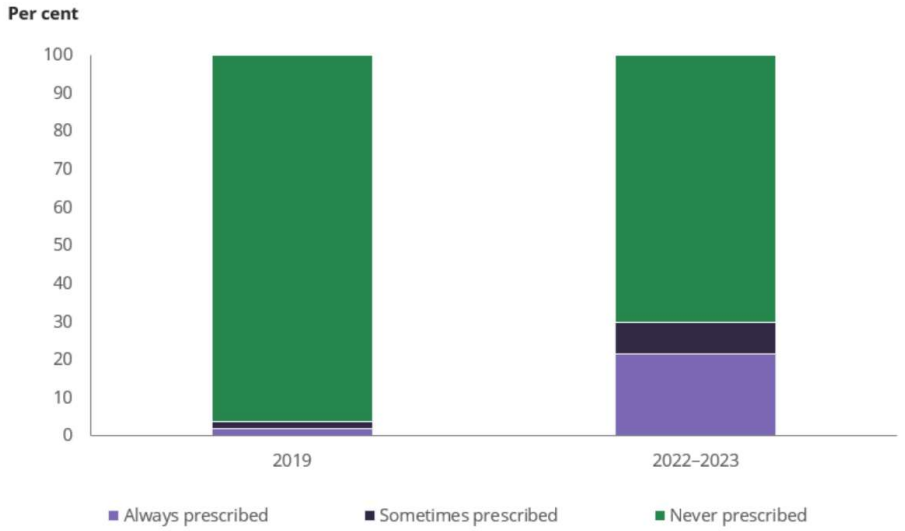
12 March 2024


1921-2021
RELATIONSHIPS
RESPECT
OPPORTUNITIES

Medicinal cannabis use in Australia

- In 2022–2023, 3% (700,000) of people in Australia had used cannabis for medical purposes in the previous 12 months.
- The proportion of people using cannabis for a medical purpose **with a prescription** is increasing:
  - In 2019, only 1 in 50 people who used cannabis for medical purposes had always had it prescribed by a doctor.
  - In 2022–2023, this increased to 1 in 5 people always had their medical cannabis prescribed by a doctor.

Cannabis prescription status for people who had used cannabis for medical purposes in the previous 12 months, 2019 and 2022–2023



Note: for people aged 14 and over
Source: AIHW and NDSHS 2022–2023, Table 8.1.

Australian Government
Department of Health and Aged Care

Office of Drug Control Update

Avi Rebera
Assistant Secretary
ACannabis
12 March 2024

Role of the Office of Drug Control (ODC)

- The ODC is responsible for:
  - Regulating import, export and manufacture of controlled drugs.
  - Regulating cultivation, production and manufacture of medicinal cannabis.
  - Reporting on activities to the International Narcotic Control Board.

- Exercises powers conferred through international treaties and domestic legislation and regulations.

Cannabis* Imports into Australia

Country of Origin	2021 Imports (kg)	2022 Imports (kg)
Canada	5,792	21,201
Denmark	195	868
Germany	9	858
Portugal	58	839
South Africa	60	600
New Zealand	51	144
Israel	420	141
Jamaica	129	119
Columbia	168	51
North Macedonia	95	33
Other Countries	196	33
Total	**7,173**	**24,887**

**Cannabis: means the flowering or fruiting tops of the cannabis plant*

Largest Source- Canada

Greatest % ⬆

(9,443%)

247% ⬆

from 2021 to 2022 totals

Australian Cannabis* Exports

Destination Country	2021 Exports (kg)	2022 Exports (kg)
Germany	1290	935
United Kingdom	131	407
New Zealand	5	167
France	-	1
Total	**1426**	**1510**

**Cannabis: means the flowering or fruiting tops of the cannabis plant*

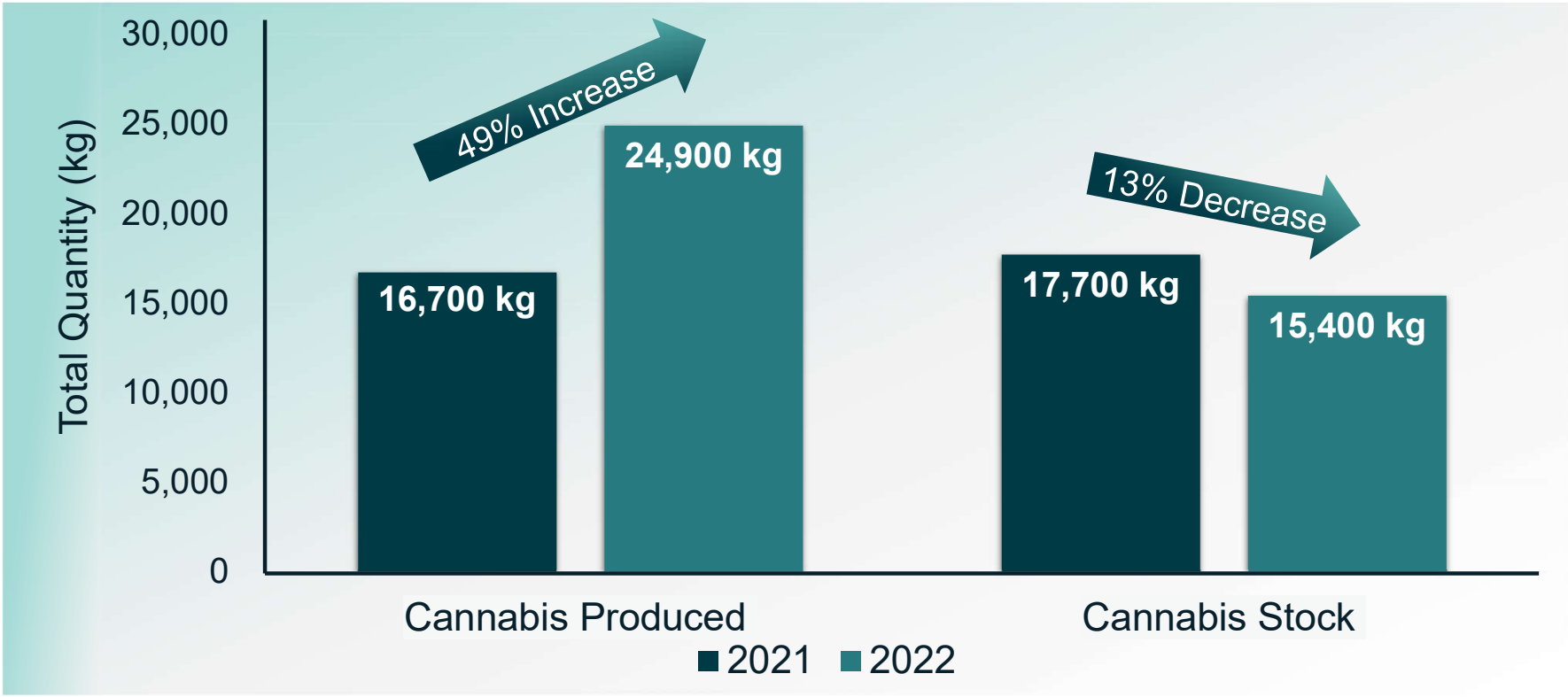
Greatest % ⬆
(3,240%)

Largest export (kg)

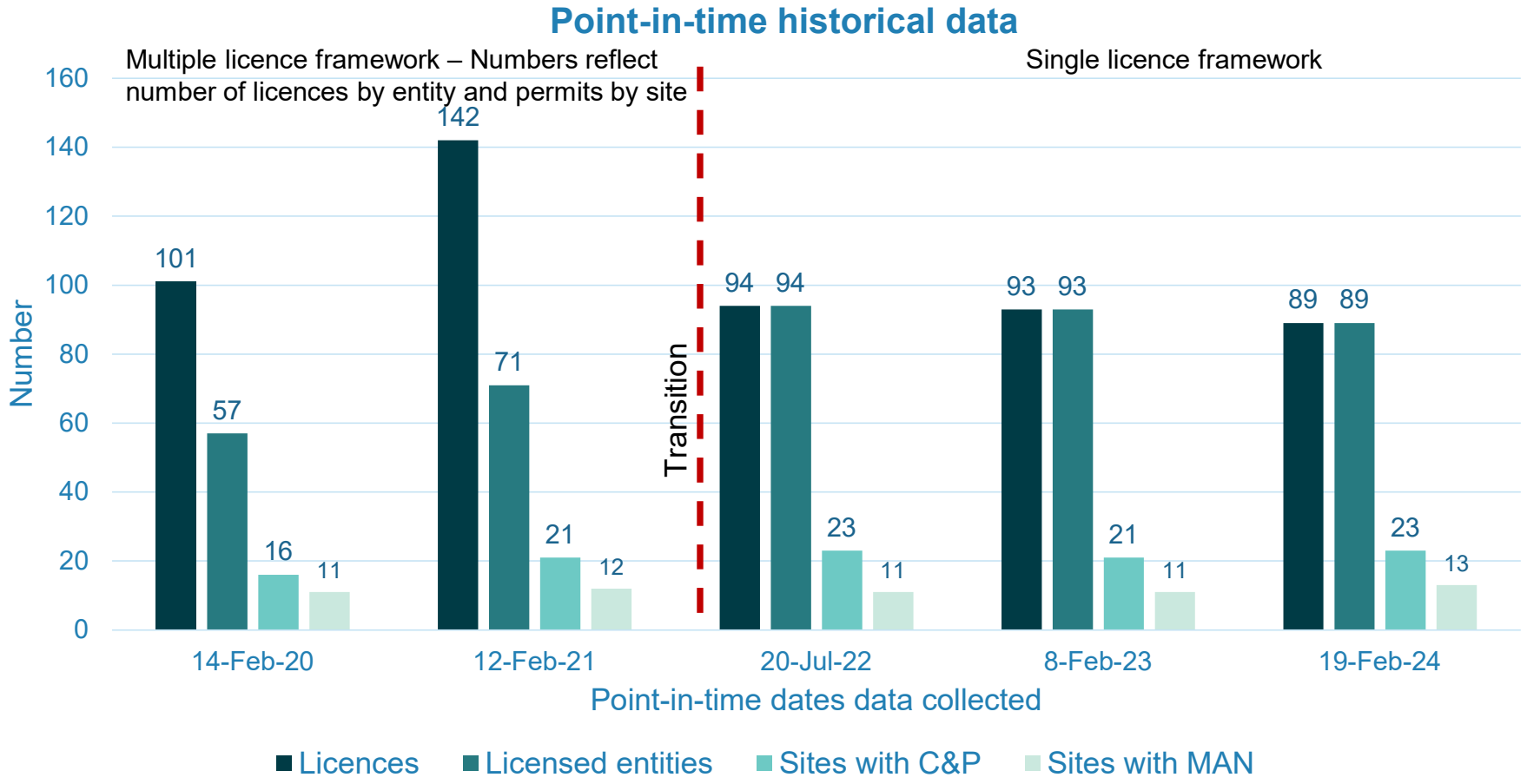
6% ⬆

from 2021 to 2022 totals

Australian Cannabis Production and Stock



Snapshot of licenced entities and permit numbers



ODC Monitoring and Compliance

- Monitor medicinal cannabis cultivation, production and manufacture licence and permit holders.
- Inspections and education campaigns - increase licence and permit holder's knowledge of their regulatory obligations; and to prevent diversion into the illegal market.
- Engage with State and territory regulators and law enforcement agencies.
- Recently implemented:
  - online tip off recording form
  - Risk Management Framework- provide transparency on our approach to risk-led monitoring and compliance activities.

The 3 main findings from compliance inspections relate to:

- Security of site and material
- Record keeping practices
- Waste management and disposal

Cannabis Waste Management Compliance

- Cannabis waste is any remaining material discarded from the cultivation, production, or processing of cannabis.
- Considered disposed once the material has been denatured and contains less than 1% THC.
- ODC provides guidance to permit holders regarding management of waste.
- The **licence holder must**:
  - have procedures in place to ensure all cannabis that is not to be manufactured into a medicinal product is disposed of or destroyed in a safe and secure manner.
  - provide details of the method of destruction and any arrangements with third parties to dispose of or destroy cannabis.
  - have arrangements in place with emergency services, police and local government authorities to deal with disposal or destruction of cannabis.

Waste Management Survey

- Only 20% of respondents tested their waste product to ensure it is denatured of THC.
- Entities choosing to compost should ensure THC levels are low in their waste content.
- The ODC aims to further educate industry on the importance of waste management and associated risks of diversion.
- Enforcement actions may be taken for incorrect waste management breaches.

Regulation of vapes – ODC's role

- The ODC regulates the import of certain substances and goods under the Customs (Prohibited Imports) Regulations 1956 (PI Regulations).
- Recent amendments to the PI Regulations requires a licence and permit to import vaping goods.
- For medicinal cannabis vaping goods, the importer must comply with applicable Therapeutic Goods Administration (TGA) and ODC requirements.

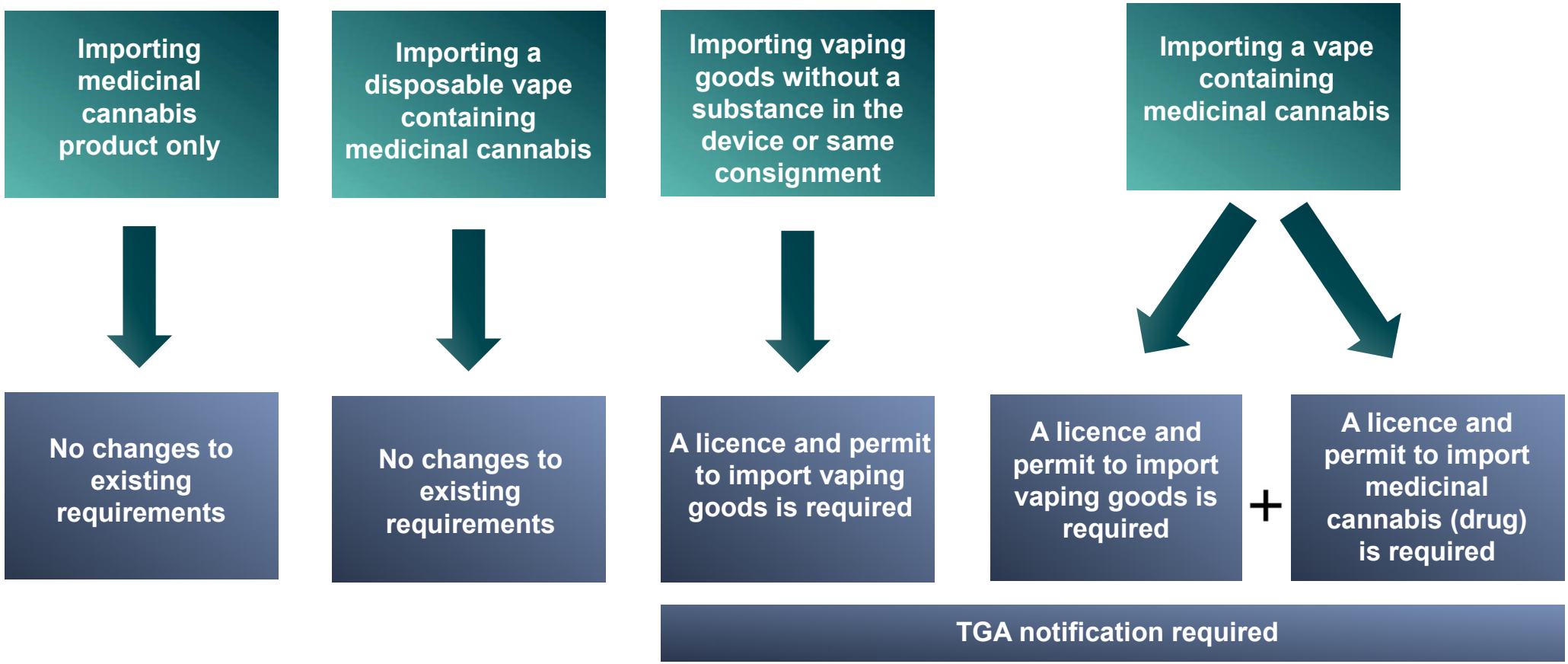
Vape: a device that generates or releases (using a heating element and by electronic means) an aerosol, vapour or mist for direct inhalation by its user. This includes parts of the vape including batteries (e.g. 510 batteries) that provide the electronic mechanism to heat the element to produce the aerosol, vapour or mist.

Vape accessory: a cartridge, capsule, pod, vial, dropper bottle, drip bottle or other vessel that contains, or designed to contain, a vaping substance.

Vaping substance: a liquid or other substance intended for use in a vape, or nicotine in solution in any concentration.

https://www.odc.gov.au/importers/importing-vaping-goods-australia/importing-nicotine-vaping-goods-australia

Impact of vaping reforms on medicinal cannabis importers- Scenarios



Changes to Fees and Charges

- Cost recovery for the Medicinal Cannabis Scheme.
- Indexed annually in line with Government's Charging Framework.
- 2024-25 fees and charges will increase between approx. 1.1% and 2.7%.
- Government has approved the indexation for 2024-25.
- Effective from 01 July 2024.
- Changes to the regulations are currently being drafted.
- ODC will publish a new Cost Recovery Implementation Statement.

Making it easier to do business with us

Over the coming year we will be transforming the way we support you to do business.

Online industry portal

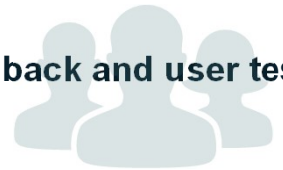
Digital case management system

Transparency | *Risk-based regulation* | *Reduced regulatory burden on industry*

ODC Transformation: Consultation & Support

We value your input and are engaging with stakeholders in preparation of the initial portal launch in mid-2024. This will include:

Direct Engagement



Feedback and user testing

ODC website updates

Demonstrations and training sessions

User information

Technical support

ODC Newsletter

- Developing a periodic newsletter to further support industry stakeholders.
- Relevant information and updates relating to ODC activities, including any updates relevant to medicinal cannabis.
- Option to subscribe to the mailing list for the newsletter.
- Stay tuned!

Thank you

https://www.odc.gov.au/

Regulatory update from the Therapeutic Goods Administration (TGA)

Professor Robyn Langham AM

Chief Medical Adviser

Therapeutic Goods Administration (TGA)

Session overview

Patient access

- Access pathways
- Patient access data

Challenges

- Telehealth services and closed loop prescribing
- Clinical management decisions
- Compounding and off-label prescribing

Future directions

- Low dose cannabidiol
- Expert Working Group

How is medicinal cannabis accessed?

- Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied in or exported from Australia unless exempt from being entered in the ARTG, or otherwise authorised by the TGA.

- Medicinal cannabis products are unapproved products
  - With the exception of two products (Epidyolex and Sativex).

- Unapproved goods have not been evaluated by the TGA for quality, safety and efficacy.

- At present, most medicinal cannabis products are supplied under the exemptions available in the Act that enable the lawful supply of unapproved therapeutic goods in Australia.

The unapproved access pathways

Authorised Prescriber (AP) scheme		
Standard Pathway	Application pathway (can only be accessed by a registered medical practitioner)	Medical practitioner must have their application endorsed by human research ethics committee (HREC) or endorsed by a specialist college prior to submitting an application to the TGA.
Established History of Use Pathway 12B(1B/C)	Application pathway (can only be accessed by a registered medical practitioner)	HREC or specialist college endorsement is not required prior to submitting an application to the TGA. Products must be included in the Authorised Prescriber established history of use list.
Special Access Scheme (SAS)		
Category A	Notification pathway (can only be accessed by a registered medical practitioner)	For patient who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
Category B	Application pathway (can be accessed by certain health practitioners)	The applicant must provide a suitable clinical justification for the use of the therapeutic good, including reasons why products included in the ARTG are not suitable for treatment.

Prescriber responsibilities and conditions in accessing unapproved therapeutic goods under the SAS and AP scheme

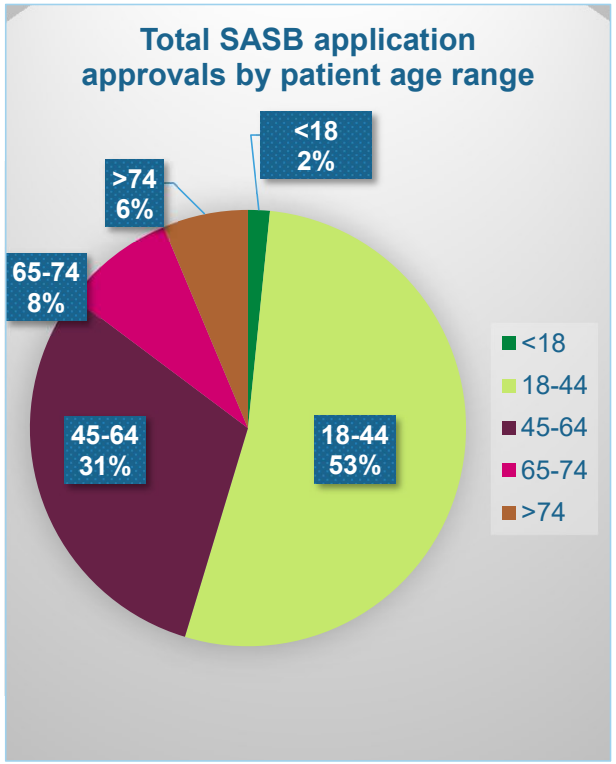
- Use in exceptional circumstances where the prescribing health practitioner has first considered other appropriate treatment options included in the Australian Register of Therapeutic Goods.
- Consider the known and unknown risks involved with the drug and understand the medico legal risks in prescribing an unapproved drug.
- Adhere to relevant standards of good medical practice and obtain informed patient consent.
- Report adverse events or defects associated with the use of the ‘unapproved’ therapeutic goods to the TGA.
- Comply with state and territory requirements

Key patient access statistics

- As of 31 January 2024, **over 1,179,000 patients** were reported to have been authorised to access a medicinal cannabis product through the SAS and AP scheme.

- More than **5,700 individual medical and nurse practitioners** and **2,480 Authorised Prescribers** have been approved to prescribe medicinal cannabis to patients.

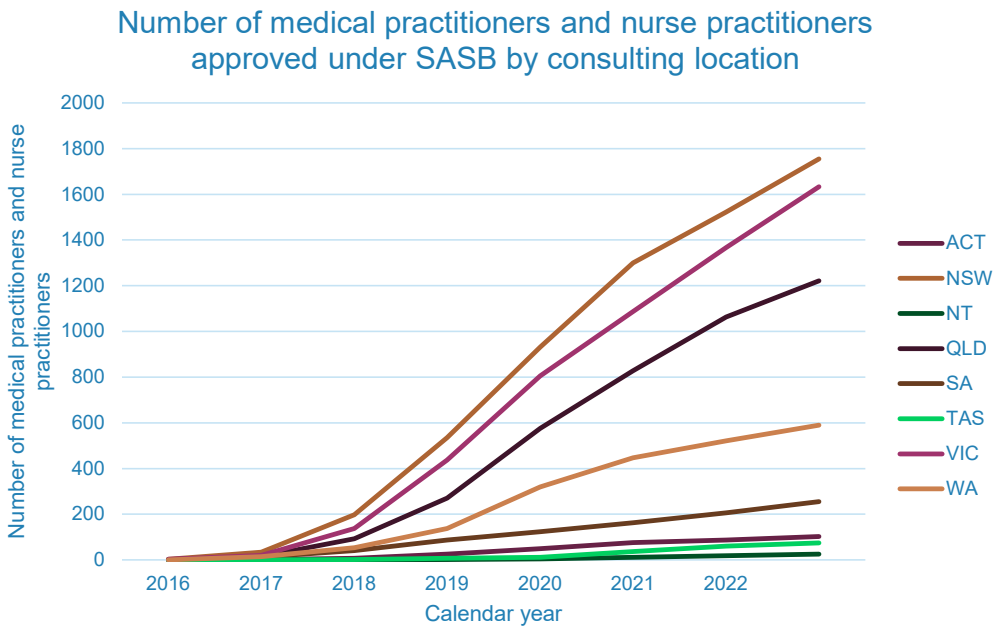
Patient access data – SAS category B data (2016 - 2023)

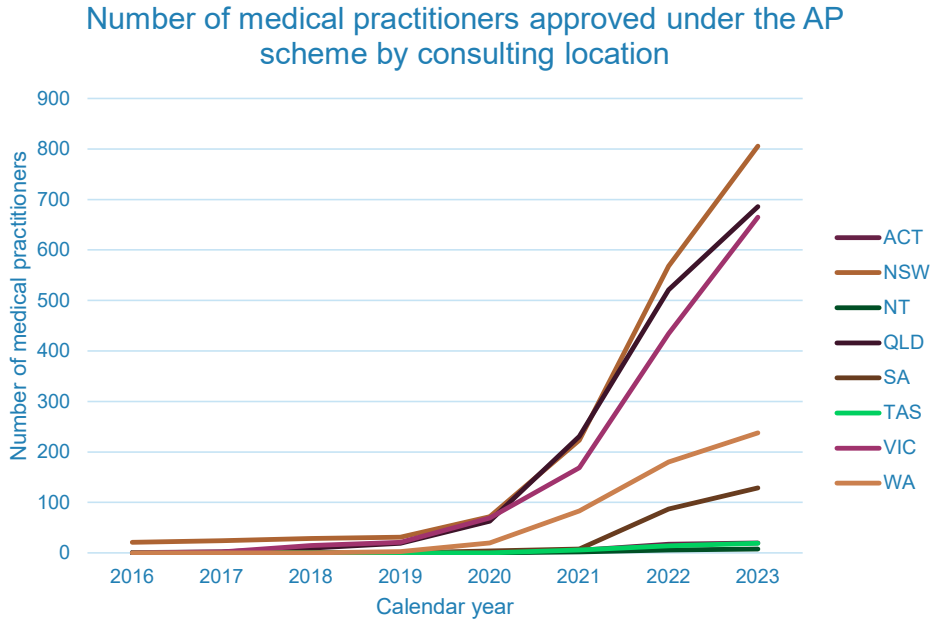


Top 10 dosage forms	Number of applications approved	Percentage of total approvals
Oral Liquid	272,020	58.87%
Herb, dried (for vaporisation)	124,417	26.93%
Vaporisation	23,179	5.02%
Inhalation	18,028	3.90%
Capsule	9070	1.96%
Spray	4819	1.04%
Wafer	1631	0.35%
Lozenge	1332	0.29%
Spray, solution	1215	0.26%
Pastille	1965	0.43%

Top 20 indications	Number of applications approved	Percentage of total approvals
chronic pain	236,537	51.11%
Anxiety	119,103	25.74%
Sleep disorder	25,074	5.42%
Cancer pain and symptom management	12,241	2.65%
Post Traumatic Stress Disorder (PTSD)	10,162	2.20%
Insomnia	8626	1.86%
Depression	7726	1.67%
Neuropathic pain	7641	1.65%
Attention deficit hyperactivity disorder (ADHD)	4450	0.96%
Arthritis	3577	0.77%
Autism spectrum disorder (ASD)	3375	0.73%
Epilepsy	2810	0.61%
Migraine	2686	0.58%
Fibromyalgia	2495	0.54%
Seizure management	1616	0.35%
Parkinson's disease	1346	0.29%
Multiple Sclerosis (MS)	1138	0.25%
Spasticity	784	0.17%
Palliative care	778	0.17%
Anorexia	708	0.15%

Patient access data – SASB and AP prescriber data (2016 - 2023)





Unapproved goods- current challenges

- The TGA met with Ahpra and state/territory representatives in January 2024.

- A number of key concerns were raised:
  - Telehealth services for complex interactions, especially where prescribing is involved.
  - Clinical management decisions and guidance alignment
  - The TGA has concerns in relation to the closed-loop prescribing business models (‘one-stop shops’).
  - Broader concerns- compounding and off- label prescribing.

Future Directions

Low dose CBD update

- Since 15 December 2020, certain low dose CBD preparations have been down-scheduled from Schedule 4 to Schedule 3.
- Currently there are no TGA approved products on the ARTG that meet the Schedule 3 criteria.
- Companies may lodge an application to the TGA for inclusion of a product in tl ARTG.

Policy advice

- Formation of Medicinal Cannabis Expert Working Group
- The EWG will commence in March 2024 for an initial 2-year term, and meet 4 times a year face-to-face or by videoconference

Current compliance context

- Unlawful advertising of medicinal cannabis is a focus area for TGA compliance activities.
- Medicinal cannabis, a prescription-only medicine, cannot be advertised to the public.
- Examples of non-compliance include:
  - advertising of health services that has indirectly or directly reference medicinal cannabis.
  - advertising that references serious conditions or diseases, which are prohibited or restricted representations.
- In December 2023, the TGA published updated *Advertising Guidance for businesses involved with medicinal cannabis products.*