Australian Government

Australian Government response to the Senate Community Affairs References Committee report:

Inquiry into Current barriers to patient access to medicinal cannabis in Australia

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Senate Community Affairs References Committee: Inquiry into Current barriers to patient access to medicinal cannabis in Australia

Government Response

Recommendation 1: The committee recommends that the Department of Health, in collaboration with the Australian Medical Association, the Royal Australian College of General Practitioners and other specialist colleges and health professional bodies, develop targeted education and public awareness campaigns to reduce the stigma around medicinal cannabis within the community.

Response: Noted. The Department will assess the interest of the AMA and RACGP and other colleges in developing education and public awareness campaigns. If there is interest from the AMA, RACGP and other health professional bodies in developing such campaigns, funding arrangements would need to be identified in competition with other public health priorities in the wake of the COVID-19 pandemic.

Recommendation 2: The committee recommends that the Department of Health allocate funds to relevant medical colleges and peak bodies to support the development and delivery of accredited face-to-face and online training programs on medicinal cannabis for medical practitioners.

Response: Noted. The demand for such courses needs first to be established, along with the preparedness of the medical colleges to deliver them. Funding for such training programs would need to be identified in competition with other public health priorities in the wake of the COVID-19 pandemic.

Training courses should have a broader and more integrated focus on management of specific conditions rather than focusing solely on the use of medicinal cannabis or other pharmacological interventions.

Recommendation 3: The committee recommends that the Australian Medical Council, as part of its role in the accreditation of Australian medical education providers, make mandatory the inclusion of modules on the endocannabinoid system and medicinal cannabis in curriculums delivered by primary medical programs (medical schools).

Response: Noted. The recommendation is a specific request to the Australian Medical Council (AMC) to mandate the teaching of the endocannabinoid system and the pharmacology and clinical uses of medicinal cannabis in the medical school curriculum. The Government has no mandate over the AMC and can only encourage action. Further, the AMC does not specify particular parts of the curriculum. It instead sets out "Accreditation Standards for Primary Medical Education Providers and their Program of Study"**.**

Under Standard 3, it states "The curriculum includes the scientific foundations of medicine to equip graduates for evidence- based practice and the scholarly development of medical knowledge., while under Standard 6, it states "The Medical education provider regularly monitors and reviews its medical program including curriculum content, quality of teaching and supervision, assessment and student progress decisions. It manages quickly and effectively concerns about, or risks to, the quality of any aspect of the medical program.

The AMC may consider that through its Medical School Accreditation Committee that Accreditation assessment teams seek evidence for the teaching program having included the endocannabinoid system and medicinal cannabis in their response to these standards.

Recommendation 4: The committee recommends that the Department of Health commission the development of a suite of printed and online resources for patients, aimed at explaining the regulatory framework and process to access medicinal cannabis.

Response: Accepted.

The Department has developed a new video and printable A4 infographic to explain the process to access medicinal cannabis from a patient perspective. These resources were published on 25 September 2020 as part of a new 'information for consumers' page on the Therapeutic Goods Administration (TGA) website. This page brings together new and existing consumer resources, including a 2018 blog post titled 'Consumer story: Caitlin and medicinal cannabis' and a 2019 blog post titled 'Introduction to medicinal cannabis regulation in Australia'. Consumer representative organisations have been notified of the new resources, and they have been shared on the TGA Facebook and Instagram channels.

Recommendation 5: The committee recommends that, if after 12 months from the tabling of this report the Commonwealth Government through the Therapeutic Goods Administration has failed to address the barriers to appropriate, regulated patient access to medicinal cannabis in Australia, a new Independent Regulator be considered, using the Regulator of Medicinal Cannabis Bill 2014 as a basis.

Response: Not accepted. The Government does not support the creation of separate regulatory processes for access to cannabis medicines as the current architecture has been readily adapted to medicinal cannabis access. An additional body would be duplicative and inefficient and would create uncertainty and delays in approval times for both the local medicinal cannabis industry and for patients.

Creation of a separate organisation would also potentially hinder patient access in the medium term, as it would make it harder for products to become TGA-registered medicines (and thus potentially be eligible for PBS subsidy). Furthermore, it is unclear what the trigger ought to be for the Government to consider a different model in 12 months time.

The 2016 amendments of the *Narcotic Drugs Act 1967* are consistent with Australia's international obligations, including under the Single Convention on Narcotic Drugs, 1961. These amendments to the Narcotic Drugs Act and existing provisions within the *Therapeutic Goods Act 1989* provide a scheme allowing for the controlled supply of cannabis for medicinal and scientific purposes. Further, in implementing the recommendations of the 2019 Independent Review of the Narcotic Drugs Act 1967 the Government is committed to addressing the barriers to patient access to medicinal cannabis in Australia.

Recommendation 6: The committee recommends that the Therapeutic Goods Administration review and improve its online resources for health professionals relating to the regulations and processes for prescribing medicinal cannabis through the Special Access Scheme and Authorised Prescriber pathways.

Response: Accepted.

The Department has developed two new videos to explain the processes for accessing medicinal cannabis from a health professional perspective. The first video provides an overview of the Special Access Scheme and Authorised Prescriber pathways. The second video is a more detailed introduction to the Special Access Scheme. These resources were published on 25 September 2020 as part of a new 'information for health professionals' page on the Therapeutic Goods Administration (TGA) website. This page brings together new and existing resources for health professionals. A range of health professional groups

have been notified of the new resources, and they been shared on the TGA LinkedIn and Twitter channels.

The Department has also funded NPS MedicineWise to produce online resources for patients and health professionals. Ten resources are available on the NPS MedicineWise website, see https://www.nps.org.au/consumers/medicinal-cannabis-explained and https://www.nps.org.au/professionals/medicinal-cannabis-what-you-need-to-know.

1. Is Medicinal Cannabis suitable for me?
2. Frequently Asked Questions – Medicinal Cannabis: What would you like to know?
3. Frequently Asked Questions – Medicinal Cannabis: Process for prescribers
4. Frequently Asked Questions – Medicinal Cannabis: Process for dispensers
5. Frequently Asked Questions – Medicinal Cannabis: Seven questions pharmacists are asking
6. Evidence Summary – Medicinal Cannabis: Chronic non-cancer pain
7. Evidence Summary – Medicinal Cannabis: Multiple Sclerosis
8. Evidence Summary – Medicinal Cannabis: Nausea and vomiting
9. Evidence Summary – Medicinal Cannabis: Palliative Care
10. Evidence Summary – Medicinal Cannabis: Epilepsy in paediatric and your adult patients

The Government recognises the importance of the currency of these resources and the need to factor emerging evidence in medicinal cannabis.

Recommendation 7: The committee recommends that the Therapeutic Goods Administration immediately clarify the clinical justification requirements of Special Access Scheme Category B in its instructions to prescribers.

Response: Accepted.

The TGA website was updated in July 2020 to include information for prescribers clarifying the clinical justification requirements for SAS Category B applications. This section (www.tga.gov.au/medicinal-cannabis-information-health-professionals) outlines that the justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

Recommendation 8: The committee recommends that the Department of Health make amendments to the Special Access Scheme Category B pathway to allow for approval of:

- **multiple medicinal cannabis products in a single application; and/or**
- **medicinal cannabis as a class of drug for the treatment of a patient for a particular indication.**

Response: Accepted in part (first sub-recommendation accepted, second recommendation not accepted).

It is understood that on some occasions, a SAS B approved product has not been available once the prescriber has received the approval and an order through a pharmacist is made. In these cases, the prescriber can already clone the previous application in the online system and change the product for subsequent approval.

In situations where multiple products are to be concomitantly prescribed for the same patient, the Department will investigate how to make multiple medicinal cannabis products able to be approved in a single application, provided that the alternative products are of similar composition. Regulatory and IT system changes may be required to implement this change.

The second sub-recommendation is not accepted by Government on the grounds of clinical safety. Medicinal cannabis cannot be considered as a single interchangeable class of drug. Both the composition and dose of any medicine are critical. Medicinal cannabis products can vary significantly in their concentrations of psychoactive THC and non-psychoactive CBD for example. It would be quite dangerous to prescribe a child with Dravet's syndrome a product with 20 % THC and zero CBD for example, instead of a defined dose of CBD.

Recommendation 9: The committee recommends that the Department of Health modify the operation of the Authorised Prescriber scheme for health professionals seeking to prescribe medicinal cannabis to ensure that:

- **completion of an accredited medicinal cannabis course be a requirement to obtain Authorised Prescriber status;**
- **relevant specialist colleges be resourced to grant Authorised Prescriber status to their members;**
- **the pathway to authorised prescriber status through the National Institute of Integrative Medicine be clarified and communicated to doctors; and**
- **authority be granted to prescribe all medicinal cannabis products, rather than on a product-by-product basis.**

Response: Accepted in part. The Government will examine options for reform to the Authorised Prescribed Scheme to make it more attractive to regular prescribers of particular medicines under SAS B. These may include changes such as the TGA being able to approve individual Authorised Prescribers as well as institutional human research and ethics committees, ability to prescribe a wider number of medicines and doses of those medicines in a single authorisation, simplification of the application requirements and greater promotion of the scheme. As some of these changes would require changes to the *Therapeutic Goods Act 1989*, these will need to be considered by the Parliament in due course.

However, the Government does not believe that attendance at a brief course, say for a few hours or a day, is sufficient qualification for Automatic Prescriber status. The Government will investigate whether the reluctance of specialist colleges to provide Authorised Prescriber approvals is a question of resourcing or rather a preference of the colleges for not being seen to oversee individual physicians' prescribing practice. The National Institute of Integrative Medicine is one of a number of organisations that have granted authorised prescriber status and it would be inappropriate for the Department of Health to actively promote this organisation over others.

Further, it is important to ensure any training courses take into account the broader management of specific conditions rather than an isolated approach to medicinal cannabis use.

Recommendation 10: The committee recommends that the COAG Health Council develop a National Framework for Medicinal Cannabis Access to set out goals for further harmonisation of Commonwealth, state and territory legislation to ensure that there are appropriate, clear and consistent regulatory pathways for accessing medicinal cannabis in Australia into the future.

Response: Noted. Significant progress has already been made to streamline and simplify regulatory processes relating to access unregulated medicinal cannabis products.

Since July 2018, prescribers in most jurisdictions have been able to submit applications via an online portal, replacing the previous paper based process. The online system has also enabled integration of Commonwealth and State and Territory regulations into the same application. This has effectively created a 'one-stop shop' for prescribers and avoids them having to submit applications through multiple channels. In addition, several States and Territories have made changes to their respective regulations to further streamline access to these medicines.

This has resulted in the approval times for complete applications being reduced from several weeks to a maximum of 48 hours. This improved and streamlined process has facilitated a large increase in the number of applications being approved as evidenced by the table below.

Up to 31 December 2020, the TGA has approved over 67,000 SAS Category B applications for unapproved medicinal cannabis products. A breakdown of the number of SAS Category B approvals by month since January 2018 is provided below:

	2018	**2019**	**2020**
January	60	670	3148
February	36	738	3568
March	54	1043	3926
April	89	1108	3378
May	132	1370	4133
June	146	1566	4630
July	188	2207	5564
August	229	2889	5270
September	237	2910	6206
October	331	3592	5972
November	567	3403	6356
December	490	3678	5630

The Government will continue to work collaboratively with the States and Territories to identify continued and greater alignment of regulatory pathways for access medicinal cannabis further improvements through the appropriate channels.

Recommendation 11: The committee recommends that the Tasmanian Government immediately join all other jurisdictions in participating in the Therapeutic Goods Administration's single national online application pathway for accessing unregistered medicinal cannabis and reducing state-based requirements for medicinal cannabis approval.

Response: Noted. The Commonwealth has a standing offer for Tasmania to join the online scheme, subject to Tasmania agreeing to process applications within a 48 hour time period. This condition was outlined to all jurisdictions upon the creation of the online portal in 2018. All jurisdictions currently participating in the online scheme agreed to this

requirement prior to joining. Participating jurisdictions have been processing applications in a timely fashion, in some cases in a matter of hours.

The decision whether or not to take part in the national scheme is ultimately one for the Tasmanian government to make. The Commonwealth stands ready to work with the Tasmanian Government on joining the online scheme, subject to the condition outlined above.

Recommendation 12: The committee recommends that the Therapeutic Goods Administration, as a matter of priority, conduct broad public consultation on the future scheduling of cannabidiol and other non-psychoactive cannabinoids.

Response: Accepted in part. Public consultation has been undertaken for two rescheduling proposals for cannabidiol. The first round of public consultation on the proposals was open from 24 April 2020 to 22 May 2020 (see www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-acmsaccs-meetings-june-2020). The second round of consultation, following an interim decision on these proposals, was open from 9 September 2020 to 13 October 2020 (see www.tga.gov.au/scheduling-decision-interim/notice-interim-decisions-proposed-amendments-poisons-standard-acms-and-joint-acms-accs-meetings-june-2020). A final decision on these two rescheduling proposals was announced on 15 December 2020. The decision was to amend the current Poisons Standard to down schedule cannabadiol to allow greater access through a new Schedule 3 (Pharmacist Only Medicine) entry in accordance with specified requirements. Further details are provided under Recommendation 13.

The scheduling of other non-psychoactive cannabinoids may be considered in the future if evidence becomes available to support their safe use.

Recommendation 13: The committee further recommends that, as soon as practicable after a safety review and public consultation process is completed, the Department of Health make any appropriate application to the Advisory Committee on Medicines Scheduling in relation to the down-scheduling or de-scheduling of cannabidiol and other non-psychoactive cannabinoids.

Response: Accepted in Part.

Two proposals for rescheduling of cannabidiol (CBD) underwent public consultation, and were considered at the 24 June 2020 meeting of the joint Advisory Committee on Medicines and Chemicals Scheduling. One proposal initiated by the Department was for down-scheduling of low dose cannabidiol to Schedule 3 (Pharmacist Only) medicine,

while a second proposal from a private applicant was for removal of pure cannabidiol from the Poisons Standard.

On 15 December 2020, the decision maker (a senior medical officer of the Department of Health, acting as a Delegate of the Secretary) confirmed the interim decision to down-schedule certain low dose CBD preparations from Schedule 4 (Prescription Medicine) to Schedule 3 (Pharmacist Only Medicine).

From 1 February 2021, this decision will allow TGA approved low-dose CBD containing products, up to a maximum of 150 mg/day, for use in adults, to be supplied over-the-counter by a pharmacist, without a prescription. The decision limits over-the-counter supply to only those products that are approved by the TGA and included on the Australian Register of Therapeutic Goods (ARTG). The decision also outlines additional limits on dosage form and packaging requirements, including pack size and child resistant closures.

Information on the TGA's safety review of low dose CBD, which informed the interim decision, is available at: www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf.

In the final decision, the decision maker increased the maximum daily dose proposed in the interim decision from 60 mg/day to 150 mg/day. This increase follows further consideration of safety information, the public submissions on the interim decision and the additional advice of the Joint Committee of the Advisory Committees for Medicines Scheduling and Chemicals Scheduling at the November 2020 meeting.

The reasons for the final decision can be found on the TGA website: https://www.tga.gov.au/scheduling-decision-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-cannabidiol. Information on the TGA's safety review of low dose CBD, which informed the interim decision, is available at: www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf.

Recommendation 14: The committee recommends the Australian Government immediately review the resourcing and staffing levels of the Office of Drug Control to ensure licence applications are processed without delays.

Response: Accepted.

As part of the 2020-21 Budget, the Office of Drug Control received addional ongoing funding to undertake medicinal cannabis regulatory functions. The Australian Government is investing $1.7 million (in addition to the $21.9 million from industry cost

recovery) over four years for the Office of Drug Control. The Budget provides for funding that is proportionate to the demand for (and regulatory fees paid by applicants and licensees) licences and permits authorising the cultivation, production and/or manufacture of medicinal cannabis. Funding also aligns with the effort involved in the regulation of the medicinal cannabis scheme.

This will enable:

- effective and timely regulation through the assessment of applications received under the Scheme
- delivery of a robust and responsive compliance monitoring and enforcement framework to mitigate the risk of diversion of cannabis and ensure compliance by licence holders with the Act, and
- maintenance of Australia's status as compliant with its obligations under the Single Convention on Narcotic Drugs 1961.

Overall staffing includes about 20 ASL staff which will increase to about 32 ASL by 2023-24 financial year. This increase reflects the workload associated with regulating the scheme and is based on fees and charges recovered through the scheme.

To ensure appropriate staffing and resourcing levels, the Department, through the Office of Drug Control, concluded a thorough review of the charging framework earlier in 2020. This review included assessing tasks associated with the regulatory functions, determining the average efficient time spent on each task and seeking feedback from industry and other stakeholders through an extensive consultation process. The charging review led to changes to fees and charges. These changes which were implemented on 15 July 2020 and 1 November 2020 which will ensure cost recovery from industry will match the resources required to regulate the medicinal cannabis scheme.

Recommendation 15: The committee recommends the Australian Government support the World Health Organization Expert Committee on Drug Dependence's recommendations for changes to the scheduling of cannabis and cannabis-related substances in international drug control conventions.

Response: Accepted in Part. On 2 December 2020, Australia voted at the Commission on Narcotic Drugs (CND) on six recommendations concerning the scheduling of cannabis and cannabis related substances, made by the World Health Organisation (WHO) in January 2019 to the CND.

The CND adopted the first recommendation to delete cannabis and cannabis resin from Schedule IV of the Single Convention on Narcotic Drugs, 1961, as amended (Single

Convention), which has the effect of recognising that cannabis is being used for medical purposes by many countries. Australia voted in favour of this recommendation.

The CND however rejected the remaining five recommendations. Australia was not supportive of the sixth WHO recommendation, as it would remove international border controls for THC preparations. This recommendation was also not consistent with the Australian domestic status of THC (a Schedule 8 controlled drug).

For Australia, the benefit of the WHO recommendations, where they have been adopted, would have ensured consistency with other countries on the international control framework as they apply to cannabis and cannabis related substance. Despite the rejection of five of the WHO recommendations, all parties are committed to the Single Convention and CND.

The CND adoption of the WHO recommendation to delete cannabis and cannabis resin from Schedule IV of the Single Convention and the rejection of five of the six recommendations are not expected to have any impact on Office of Drug Control stakeholders. There is also no impact on Australian scheduling in the Poisons Standard. Cannabis and its extracts for therapeutic use continue to be in Schedule 8 of the Poisons standard.

Recommendation 16: The committee recommends the Department of Health, through the Therapeutic Goods Administration and the Office of Drug Control, continue to monitor how any future changes to Australia's obligations under international drug control conventions can facilitate streamlining regulations relating to the scheduling, approval, manufacture, and handling of cannabis.

Response: Accepted. The Department of Health maintains a close working relationship with the International Narcotic Control Board (INCB) and sends a delegation to the annual sessions of the CND. Australia is obligated to implement any scheduling changes made by the CND. The Department, through Office of Drug Control, monitors all such changes and makes recommendations for any amendments to legislation.

It is noted, however, that CND's recent adoption of the first WHO recommendation to delete cannabis and cannabis resin from Schedule IV of the Single Convention has no impact on Office of Drug Control stakeholders nor on Australian scheduling of cannabis in the Poisons Standard.

Though not related to Australia's obligations under international drug control conventions, amendments have recently been made to Export Control Act 1982 and the Export Control Act 2020, through the Export Control Legislation Amendment Act

(Certification of Narcotic Exports) Act 2020 (which commenced on 23rd June 2020). These amendments ensure that Australia's international obligations under the International Plant Protection Convention can be met by providing the necessary legislative authority to issue, and regulate the issue, of phytosanitary (plant health) certificates for products that are classified as narcotic goods under Australia's Customs Act 1901. The amendments ensure government can facilitate the legitimate exports of narcotic goods from Australia through the issuance of this certification, where it is an import requirement of an overseas country that certification accompany a consignment.

Recommendation 17: The committee recommends that the Medicare Benefits Scheme Review Taskforce accept the General Practice and Primary Care Clinical Committee's recommendation to introduce a 'Level E' consultation item for general practice consultations of 60 minutes or longer, and includes this item in recommendations to the Australian Government relating to changes to Medicare Benefits Scheme items for primary care.

Response: Noted. The General Practice and Primary Care Clinical Committee (GPPCCC) is a sub-committee established by the independent, clinician-led Medicare Benefits Schedule Review Taskforce. The GPPCCC's recommendation to introduce a Medicare Level E consultation item for general practice consultations lasting 60 minutes or longer were considered by the Taskforce. The Taskforce has now finalised its recommendations to the Government related to primary care. These recommendations are presently under consideration by Government.

Recommendation 18: The committee recommends that medicinal cannabis industry peak bodies, such as Medicinal Cannabis Industry Australia and the Medical Cannabis Council, work with their members to implement compassionate pricing models for patients facing significant financial hardship in accessing medicinal cannabis products to treat their health conditions.

Response: Noted. The Government encourages industry to provide compassionate access to medicines for those patients facing significant financial hardship.

Recommendation 19: The committee recommends that, until medicinal cannabis products are subsidised though the Pharmaceutical Benefits Scheme, the Australian Government:

- **investigate the establishment of a Commonwealth Compassionate Access Subsidy Scheme for medicinal cannabis, in consultation with industry and based on the best available evidence of efficacy for certain conditions; and**

- **encourage all states and territories, through the COAG Health Council, to expand the provision of their own Compassionate Access Schemes to patients requiring treatment with medicinal cannabis.**

Response: Noted. While the Commonwealth Government does not support establishment of a subsidy scheme for medicinal cannabis or other medicines separate to the Pharmaceutical Benefits Scheme (PBS), it encourages the continuation (and expansion where possible) of existing state and territory Compassionate Access Schemes for medicinal cannabis products. The Government maintains that the most sustainable approach for potential Commonwealth subsidy of medicinal cannabis products is consideration by the independent Pharmaceutical Benefits Advisory Committee (PBAC) of products that have received regulatory approval by the TGA.

The PBS is not designed for unapproved therapeutic goods for which supply has been approved through the Special Access or Authorised Prescriber Schemes. Under the National Health Act 1953, a new medicine cannot be listed by the Australian Government on the PBS unless the PBAC makes a recommendation in favour of listing. When considering a medicine proposed for PBS listing, the PBAC is required to give consideration to the effectiveness and cost of the medicine, including by comparing the effectiveness and cost with that of alternative treatments. The Australian Government has a policy to list on the PBS all medicines recommended by the PBAC.

The PBAC's consideration against its statutory obligations needs to be informed by evidence about the clinical effectiveness and safety of the medicine when compared with alternative available treatments. The PBAC's consideration is therefore generally initiated by the pharmaceutical company responsible for a medicine making an application to it for the medicine to be considered for PBS listing.

The Government notes that manufacturers of relevant therapeutic goods often provide patients compassionate access while the company applies for reimbursement.

Recommendation 20: The committee recommends that the Australian Government, through COAG, encourage a review of state and territory criminal legislation in relation to:

- **amnesties for the possession and/or cultivation of cannabis for genuine self-medication purposes; and**
- **current drug driving laws and their implications for patients with legal medicinal cannabis prescriptions**

Response: Noted. On 29 May 2020 the Prime Minister announced replacement of COAG by the National Federation Reform Council, with decision-making by the National Cabinet. The Government does not support the provisions of amnesties for possession

and/or cultivation of cannabis through illegal sources, as there are straightforward legal means by which to obtain medicinal cannabis products on the prescription of medical doctor. Drug driving laws are legislated by the states and territories, although during 2020 the Advisory Council for the Medical Use of Cannabis is reviewing the implications for driving for patients prescribed medicinal cannabis.