Medical Cannabis Advisory Group Queensland

Patients with Life Threatening Conditions
Access to Cannabis SAS Category A

Submission: Motion to Disallow the Government's **Therapeutic Goods and other Legislation Amendment (Narcotic Drugs) Regulation 2016 [F2016L0652]** presented to the Australian Senate and House of Representatives on 7 November 2016 and other ***patient focused*** Cannabis Law Reform measures

January 2017

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Submission: Commonwealth Parliament of Australia

NOTICE OF MOTION TO DISSALLOW

Commonwealth Government's Amendments *Therapeutic Goods Regulation* presented by the (former) Minister for Health, Sussan Ley on 7 November 2016

Other Law Reform: For the Rights of all Australians to be afforded Timely Access to Cannabis for Medical and Food Purposes

Patients with life threatening conditions should not have to drag themselves through unnecessary bureaucratic obstacles at the very time when they are most vulnerable and in need of support.

Patients must come first, not private and government agendas funding research trials for corporations to patent and register single molecule cannabinoid medicines for exclusive marketing rights.

No patient or carer should have to choose between breaking an unjust law and suffering pain, disability or death.

About the Medical Cannabis Advisory Group

The Medical Cannabis Advisory Group (MCAG) is a patient driven and focused not for profit-incorporated association based in Queensland. We do not receive any government grants, and are not aligned with any political party, religious organisation, or commercial entity. All of our advocacy has been done on a pro bono basis and has been self-funded by patients and carers.

Although our group is Queensland based, the health and legal issues that we have covered in our submissions have the same impact on patients and carers in the other states and the territories.

We have been advocating and campaigning for the legal and human patients rights of all patients at a federal and state level, and want to ensure that all patients are afforded the right to timely, equitable and lawful access to cannabis that is affordable.

There is still no local supply, the overly bureaucratic patient access pathways being used are causing harm because they are unsuitable for cannabis, and the patients and the cannabis that they are actually using and want to use is still criminalised under unjust state laws because of corporate agendas and the lack of respect for the patients health and legal rights, and the doctor patient relationship.

In 2015 our campaigns and advocacy[1] bought about several precedents at a federal and state level. We fought hard for the rights of all patients to have access to cannabis medicines in a manner that was tailored to meet the individual medical needs of the patient not based on outdated policy, judgmental views, and corporate agendas.

In December 2015, the Queensland Government changed the state *Health (Drugs and Poisons) Regulation,* bringing an end to the longstanding prohibition on the use of Schedule 9 cannabis and tetrahydrocannabinols (THC) however the changes did not go far enough.

In March 2015 we also prepared applications to the Therapeutic Goods Administration (TGA) and state government for Lindsay Carter who was 16 at the time, and who was the first patient in Australia to obtain TGA and state approval to legally access dried cannabis bud for vaporising, and high THC oil to treat his brain tumour, epilepsy, nausea, cachexia and chronic pain, when these medicines were listed in **Schedule 9.** We also requested an exemption from the Queensland Attorney General for access to a compassionate supply, while Lindsay was waiting for his medicines to be imported, or for an adequate and legal supply to be made available in Australia.

[1] Proposal for Cannabis for Medical Purposes Law Reform and Interim Measures in Queensland, May 2015 at Medical Cannabis Advisory Group website at http://medicalcannabisqld.wixsite.com/medicalcannabisqld/law-reform-proposal.

[2] Submission to the Parliamentary Committee Inquiry on the Public Health (Medicinal Cannabis Bill) 2016,

In December 2015, Lindsay's case set a precedent around patient access for all Australian patients, but what has occurred in this country since has seen the debate go backwards, patient's rights trampled over and access made almost impossible because of the Federal LNP Government's (Federal Government) flawed and outdated policy behind its cannabis cultivation scheme introduced in February 2016 with unworkable patient access procedures through the TGA pathways, along with all the bureaucratic barriers that have been put in place by state governments.

During 2016, we also advocated against a state Bill in Queensland, and submitted a very comprehensive proposal outlining the flaws in the Bill, as it only had provisions for patient access to cannabis from the federal scheme and through the TGA patient access pathways, and for all intent and purpose only replaces identical medical cannabis provisions that are already being used in Queensland now, under a very bureaucratic state approval process that duplicates the TGA process. The patient access process needed streamlining, not made more difficult for patients and their doctors.[2]

Here we are 2 years on, and for many of us it has been decades of advocating for reform, with a situation that is much the same as in the other states. The Queensland Government has invested $6 million in an overseas company under a deal in which only 30 children will receive compassionate access to a cannabidiol (CBD) medicine that is not as effective as the medicines that some parents are making themselves in their own homes, while a trial into another cannabinoid, that is not even listed in the schedules has not even commenced.

There are still no provisions for cultivation under Queensland laws or in some of the other states, no local supply from under the federal cannabis scheme, patients can still only access imported cannabis medicines; and the only way to legally access cannabis in Australia, whether it's imported, or comes from a local supplier when available, is through the TGA pathways which requires the doctor to obtain TGA and state approval under convoluted bureaucratic processes.

Industry has been stifled, patients and the cannabis that they are actually using is still criminalised under unjust state criminal laws, with the debate taken back to the prohibition era because of a complete lack of respect for the rights of patients driven by narrow minded, ignorant outdated views, and political and corporate cannabidiol (CBD) agendas.

We have strongly objected to what has been occurring in Australia, with the Federal Government and state governments rushing complex legislation through parliament and making policy and regulation changes with no input from the patients, and with no or little regard for the adverse consequences for patients and their health and well being, and their carers and the family as a whole.

[2] Submission to the Parliamentary Committee Inquiry on the Public Health (Medicinal Cannabis Bill) 2016, Queensland Parliament, July 2016 http://medicalcannabisqld.wixsite.com/medicalcannabisqld/medicinal-cannabis-bill-qld

We want immediate and long-term solutions that work for all patients and their families. Any policy and reform measures must put the health, welfare and human rights of patients before profits, politics, propaganda and prejudice.

We want to see an end to the stigma and ignorance around the use of all forms of cannabis for medicines and food, and want policy and law reform measures introduced that will ensure that all Australians are afforded lawful, affordable and equitable access to cannabis medicines and hemp foods.

We want reform measures to be introduced that will cater for the individual needs of all patients regardless of their age, medical condition, financial status, whether their doctor is a GP or specialist, and whether the patient needs to use tetrahydrocannabinols (THC), dried cannabis bud for vaporising, nabiximols or cannabidiol (CBD).

We want absolute respect for the legal and human rights of all patients and full respect for the doctor-patient relationship. The decision on whether or not to use cannabis as an unapproved and unregistered medicine, when a patient or their legal guardian has given their informed consent, must lie strictly between the patient and his or her own doctor, and not be driven by outdated policy, or judgmental and ignorant views or corporate agendas.

We want equality before the law for all patients, and object to the continued use of unjust state criminal laws, and the delays and restrictions on lawful access for immediate and actual patient use. All patients, carers and genuine compassionate suppliers have a right to be afforded legal protection from being charged with criminal offences under unjust state criminal laws.

We support ground breaking research, but object to any delays and restrictions on access because of unnecessary clinical trials (that take 10 - 20 years) with the aim of registering patented single molecule cannabinoid medicines, or a cannabidiol (CBD) only agenda at the expense of patients who need cannabis and tetrahydrocannabinols (THC). No one has the right to trample over another person's health and human rights, for personal, or political or corporate agendas.

We hope that you will take the time to read our submission, and understand how the Federal Government's policy and its so-called "historic" legislative reforms, that have also been adopted and followed by the states, is causing harm and having an adverse impact on patients and carers right across Australia.

We look forward to your support for the introduction of real reform measures that will streamline access and be inclusive for all Australians who can benefit from cannabis for medical purposes and hemp products as a nutritional food supplement.

Medical Cannabis Advisory Group Queensland

Introduction

Instead of real and meaningful law reform that caters for the needs of all patients, and equitable and lawful access to cannabis that is affordable, what has occurred in this country is the Federal Government and state governments have created an illusion of reform, and in the process of so called "historic" reform, patient's rights have been stripped away.

On 1 November 2016, all the Federal Government did in regard to patient access was keep the status quo. Behind closed doors, Sussan Ley made discretionary changes to the *Therapeutic Goods Regulation 1990 (Cth)* (*Therapeutic Goods Regulation)* that stripped away patient's rights to have fast tracked access under Category A. This is discussed in more detail below, along with our calls to the Commonwealth Parliament of Australia for a Notice to Motion to have the changes disallowed.

The Federal Government's cannabis scheme does not cater for the needs of patients, and the states have only introduced laws that duplicate at a state level the TGA processes, and only delays access further or makes legal access impossible for most patients to achieve, and now some of the other states that have not legislated are also bringing in similar laws to New South Wales, Queensland and Victoria, that only duplicates the TGA process.

Throughout 2016 the Federal Government and state governments, engaged in misleading and deceptive media campaigns, stating that from 1 November 2016, doctors across Australia would be able to prescribe cannabis. On 1 November 2016 when cannabis was down scheduled to Schedule 8 "controlled substance", there was no supply available in this country for doctors to prescribe.

Even before 1 November 2016, the Federal Government and state governments started other misleading and deceptive media campaigns, around patient access and doctors prescribing cannabis.

In Queensland the government has been reporting since last year that doctors will be able to prescribe cannabis from March 2017, when they have been able to do this since December 2015, and more recently media reports state that the government is attempting to force onto patients under 25, and their doctors a corporate cannabidiol (CBD) agenda, at the expense of patients who need cannabis and tetrahydrocannabinols (THC).

The facts are, Queensland doctors have been able to prescribe cannabis and tetrahydrocannabinols (THC) under the *Health Drugs and Poisons Regulation 1996 (QLD)* since December 2015 through the SAS, and since June 2016 doctors could obtain state approval, as a patient class prescriber, if they had TGA approval as an authorised prescriber. The Queensland Bill will only replace existing and almost identical prescribing and dispensing provisions that are currently being used now by doctors and pharmacists in Queensland.

The facts are, some of the other states have had long standing provisions for access to Schedule 8 nabiximols, and access to Schedule 9 substances including cannabis, and most states have had provisions for access to dronabinol, a synthetic THC since the 1990's.

Cannabidiol (CBD) was listed in Schedule 4 as a prescription medicine in 2014, even though overseas CBD is sold online and over the counter as a food supplement, and most of the states in Australia have had provisions in state laws for hemp licenses for over a decade.

The main issues for patients has been no legal supply in Australia, the states failing to allow cultivation, and prohibiting or restricting access, and keeping patients criminalised unjust criminal laws, and leaving patients reliant on the black market unless they grow their own.

Despite all the media hype and so-called "historic" legislative reform very little has changed. What occurred, months before the Federal Government introduced its legislation into the Australian Parliament in February 2016, was a decision to keep the status quo to protect the TGA pharmaceutical model, and government funded corporate clinical trials.

The TGA launched its rescheduling proposal in January 2016 even before the Federal Government introduced its cultivation legislation into the Australian Parliament in February 2016. State health departments across Australia were well aware of the Federal Government's policy to keep the status quo.

To make it look like something was being done, the Federal Government introduced its so-called "historic" legislative reforms but the objectives from the outset were always to delay access for actual use. To achieve this cultivation licences were delayed from the beginning, and with the assistance of the states, even more barriers have been put in place that restrict and delay access under the TGA pathways.

Patients and doctors using the TGA have to jump through hoops and hurdles in order for the patient to gain access to a legal supply of cannabis medicines that is urgently needed. There is still no local supply, patients can still only access cannabis that is imported but with the state governments putting in place insurmountable barriers and convoluted bureaucratic processes, access is almost impossible for most patients, and won't be much easier when local cannabis is available as doctors still need TGA and state approval.

The Queensland Government amended and changed the health regulations in December 2015, in line with the LNP's status quo policy, without any input from patient advocacy groups. Our group was excluded even though the government had adopted in part some of our recommendations.

What has also occurred in this country over the past 2 years is a dramatic increase in the discrimination against the patients who use high tetrahydrocannabinol (THC) extracts, and who smoke or vaporize dried cannabis bud for medical purposes.

This increase in discrimination has been driven by propaganda, outdated views and ignorance by the government and some of the private sector involved in research trials with overseas companies, with the aim of patenting cannabis medicines for registration and marketing approval under the TGA process which can take 10 - 20 years.

The increase in discrimination has also been driven by misrepresentations about cannabidiol (CBD) being the good cannabinoid, and tetrahydrocannabinols (THC) as the bad cannabinoid, and reference to the cannabis that patients smoke or vaporized for medical purposes as "street cannabis" or "recreational cannabis."

This is just propaganda. There is no such thing as good or bad cannabinoid. What there is, are agendas, with tens of millions already invested in cannabidiol (CBD), and opportunists seeking to exploit the cannabis market at the expense of patients who need cannabis and tetrahydrocannabinols (THC), and when cannabidiol (CBD) hemp oils should be available as a nutritional source of food for all Australians, not as expensive prescription medicines.

Patient's rights have been trampled on; patients have been left behind and left out of the process completely for corporate and other agendas. Patient advocacy groups fighting for real reform have been excluded from the decision making process. Most patients have been left with no alternative, other than to keep breaking unjust laws, with many choosing to grow their own cannabis, or suffering pain, death or disability needlessly.

We believe that the public and the majority of Commonwealth and State and Territory Parliamentarians have been misinformed about cannabis and cannabidiol (CBD) because of corporate and other agendas, and have been confused about how the state laws interact with the Commonwealth cultivation and manufacturing licences under the *Narcotic Drugs Act 1967 (Cth)* (*Narcotic Drugs Act)* and other legislation, along with the use of the patient access pathways and the scheduling systems under the *Therapeutic Goods Act 1989 (Cth)* (*Therapeutic Goods Act)* and state health and criminal legislation.

About this submission

This submission mainly focuses on patient access for patients with life threatening conditions that will be adversely affected by the Government's amendments, and the urgency for a **Notice of Motion to Disallow** the Federal Government's discretionary amendments to the *Therapeutic Goods Regulation* currently before the Commonwealth Parliament of Australia as a disallowable instrument.

The submission also discusses other issues with the SAS, Category B and the authorised prescribers scheme, and the TGA's scheduling system which is not suitable for cannabis medicines or hemp foods, but is still being used by the Federal Government and state governments, causing harm and burdening patients, carers and doctors.

Just as important an issue that is also needs to be addressed as a matter of urgency, is the continued classification of the cannabis that patients are growing and using, and that still remains under Schedule 9 of the Commonwealth Poisons Standard 2016 (Poisons Standard), also commonly referred to as the SUSMP. The schedules under the Poisons Standard is adopted by the states in health laws and unjust state criminal drug laws, and is keeping the cannabis that patients are growing for themselves and using as medicine, and their carers, illegal and a criminal offence in every state and territory across Australia.

Patients and carers need meaningful law reform measures that cater for the needs of all patients, and not exclusionary reform measures that only cater for corporate agendas.

Change.org Petition: Malcolm Turnbull Give Patients Access Under Category A

In November 2016 we launched a change.org petition[3] after becoming aware that the Federal LNP Government had introduced its **Therapeutic Goods and other Legislation Amendment (Narcotic Drugs) Regulation [F2016L0652].**[4]

The petition has been signed by thousands of people from across Australia, and has also been supported by a number of leading patient advocacy groups from across Australia including the Medical Cannabis Users Association (MCUA), which has over 13,000 members Australia wide. Please take the time to read some of the thousands of personal comments from patients, carers, and their supporters in the community who want real reform and patient access now. You can view our petition at the link provided in the footnote below.[5]

Our petition is calling on the Prime Minister, Malcolm Turnbull and the former Minister for Health, Sussan Ley to:

1. To give patients with life threatening conditions the right to access all forms of cannabis medicines under the Category A.

2. Stop the states from putting in barriers that delay access under Category B.

3. Stop interfering with the states right to change unjust state criminal laws that put patients at risk of being arrested, charged, prosecuted and convicted for drug offences, and their medicines confiscated by police, and parents at the added risk and stress of the intervention of child services.

[3] Please see the Medical Cannabis Advisory Group's change.org petition with comments from thousands of supporters at https://www.change.org/p/malcolm-turnbull-sussan-ley-give-seriously-ill-and-dying-patients-back-their-legal-right-to-urgent-access-to-cannabis-and-stop-interfering-in-state-and-territory-rights-to-change-unjust-criminal-laws.

[4] Explanatory Statement, **Therapeutic Goods and other Legislation Amendment (Narcotic Drugs) Regulation (F2016L01652)**http://www.austlii.edu.au/au/legis/cth/num_reg_es/tgaoladr2016201601652706.html.

[5] The Queensland Medical Cannabis Collective, United in Compassion , MCUA, Weeded Warrior and WACAN.

We are also calling on the Commonwealth Parliament, and the Federal Government and all state and territory governments to adopt measures that will ensure that all patients have accessible, affordable and lawful access to cannabis medicines in a timely manner, and to address the injustice that is being caused because of outdated state criminal drug laws.
As mentioned above we have made some simple recommendations that will go towards addressing some of the short and long-term issues around patient access under the national cannabis scheme using the TGA pathways.

While we do not profess to having solutions for all of the issues around patient access or supply, we believe that our recommendations are sensible, and will go a long way towards improving and streamlining the currently unacceptable and unworkable TGA and state patient access processes.

We are also asking for an alternative model under state law as the Federal Government's commercial pharmaceutical model under the TGA may take 5 - 20 years before registered products are available.

There are also many patients that will not be catered for under the federal licencing scheme. Patients in every state need these provisions included in state law for access to a compassionate and affordable supply of cannabis from not for profits as any cannabis medicines coming from under the federal scheme will be too expensive for tens of thousands of patients on low incomes and disability pensions. This is also discussed in more detail below.

We have also made a number of recommendation below, in respect to the cannabis and tetrahydrocannabinols (THC) that patients are actually growing or making themselves and using now, and that is putting them at risk of being arrested and charged under unjust state and territory laws.

Our Recommendations under a Simple 5 Point Plan to resolve Patient Access Issues, Unjust State Laws and Licencing for Industry.

1. Notice of Motion to Disallow - Allow Access under Category A of the SAS
2. Streamline Category B
3. Streamline Authorised Prescribers
4. States to Give Exemptions to Patients, Carers and Not for Profit Compassionate Suppliers
5. Fast Track and Review Medical Cannabis and CBD Hemp Licences

We have recommended that the cannabis and tetrahydrocannabinols (THC) that the patients are growing themselves, and that is still illegal under state laws is down-scheduled from Schedule 9 in the Poisons Standard, and listed in Schedule 1 (currently empty) for the states to regulate under state health laws and regulations with provisions included for approvals for patients and carers that will provide them with an exemption from criminal offences when growing and using their own cannabis, as long as they are not selling or giving it away. This is also discussed in more detail below.

Patients should not have to choose between breaking an unjust law and suffering pain, death and disability to be able to make or access their own medicine if they are not selling it or harming anyone.

We are also calling for transparency, and an independent review or inquiry into how cannabis and patient access should be regulated under a national cannabis scheme, and under state and territory laws. We want independent and qualified patient advocates, who have no conflict of interests, to be appointed on the Federal Government's Advisory Council, and for patient advocates to always be included in any decision making processes that may impact on product supply and patient access.

Good policy and law reform must be transparent and must ensure that all patients will be catered for and are afforded the right to timely and lawful access to cannabis medicines that meets the individual needs of the patients.

This will only be achieved with input, advice and feedback from qualified patient advocates who understand cannabis and the complex legal, health and social issues that patients and carers have to live with on a daily basis.

We are asking all Members of the Commonwealth Parliament of Australia Australian Parliament to take the time to read our submission, and understand the issues that patients are trying to deal with every day. We are asking the Commonwealth Parliament of Australia to give serious and bi-partisan support to our short and sensible recommendations as set out below to rectify this unacceptable situation that is impacting on the lives of hundreds of thousands of Australian patients in every state and territory across Australia.

We want the focus to be on the needs of all patients before corporate profits and political point scoring, or any other agendas. Our recommendations are outlined below in more detail.

Patient Access Issues, Unjust Criminal Laws and Industry

1. Category A and Personal Importation

Notice of Motion to Disallow - Importance Very High

We are calling on Members of the Commonwealth Parliament of Australia to move or support a Notice of Motion to Disallow items 1 and 4 of the Government's **Therapeutic Goods and other Legislation Amendment (Narcotic Drugs) Regulation [F2016L0652]**[6] that was introduced into the House of Representatives[7] and the Senate[8] by the former Minister for Health, Sussan Ley on 7 November 2016.

[6] Explanatory Statement, **Therapeutic Goods and other Legislation Amendment (Narcotic Drugs) Regulation (F2016L01652)**http://www.austlii.edu.au/au/legis/cth/num_reg_es/tgaoladr2016201601652706.html.

[7] House Disallowable Instrument List, 7 November 2016, Australian Parliament website at http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/leginstruments/house-dissallowable-instruments.

[8] Senate Disallowable Instruments List, 7 November 2016, Australian Parliament website at http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/leginstruments/senate-dissallowable-instruments

The Government's Therapeutic Goods and other Legislation Amendment (Narcotic Drugs) Regulation is currently a disallowable instrument, and needs the urgent attention and support from all members of the Commonwealth Parliament of Australia, as there are only 5 sittings days remaining in the Senate and House of Representatives when Parliament resumes on 7 February 2017 for a vote on a Motion to Disallow the Government's amendments to the *Therapeutic Goods Regulation*.

If the Government's amendments are allowed, they will have the adverse effect of denying patients with life threatening conditions fast tracked access to cannabis medicines under Category A of the SAS. The changes also affect the Personal Importation Scheme.

Overview: Government's Amendments to the *Therapeutic Goods Regulation*

On 1 November 2016, and at the same time the Government down scheduled cannabis and tetrahydrocannabinols (THC) from Schedule 9 to Schedule 8 in the Poisons Standard, without any warning or public consultation, the Government also made discretionary amendments to the *Therapeutic Goods Regulation.*

If the Government's amendments are allowed, patients with life threatening conditions will be denied fast tracked access to all cannabis medicines under Category A of the SAS.

Instead of fast tracked access, patients will need to access all cannabis medicines under the Category B process which can take up to 6 months or even longer, as the doctor first needs Category B approval from the TGA, and then needs to apply for state approval from their state or territory health department, under another time consuming bureaucratic process where the state duplicates the TGA process.

The Government's amendments are also inconsistent with the Government's own *Response to the Review of Medicines and Medical Devices Regulation* 2016 that was delivered by Sussan Ley in September 2016, and that reported **no changes would be made to Category A of the SAS**; and that a new Schedule of Category B products would be eligible for automatic approval, similar to the Category A - TGA notification process.

Please note: These amendments apply to all cannabis under the federal licensing scheme, and not just to imports, and are entirely separate to the amendments to the regulations under the *Narcotic Drugs Act* that were made about the same time, in regard to cultivation license requirements for fit and proper persons, and Commonwealth and state police sharing sensitive information.

The Government's changes that affect Category A, and the Personal Importation Scheme are now discussed in more detail followed by our recommendations to resolve the issues and streamline access.

Brief Overview: Special Access Scheme

Under the SAS any registered medical practitioner (general practitioner or specialist) can potentially supply any unapproved medicine to a patient on a case-by-case basis. There are no age restrictions, or restrictions on the types of medical conditions that can be treated with unapproved medicines under the SAS.

The TGA make it clear the SAS is not to be used by companies as a backdoor way to supply their products. The SAS is only for short-term supply. Companies wanting to supply long term must have the aim of registering their products on the ARTG, which can take 10-20 years as data from clinical trials is needed.

Unapproved medicines are also referred to as unregistered medicines, as they have not been given marketing approval by the TGA, and are not listed on the Australian Registrar of Therapeutic Goods (ARTG). Patients can also access medicines through the SAS that may be registered on the ARTG, but have to be imported because the company does not keep stock available in Australia, for example Sativex is the only cannabis medicine registered on the ARTG but needs to be imported.

Patient Categories

Under the SAS there are two categories of patients.

- Category A – TGA notification only
- Category B – TGA approval for all other patients

The choice of the classification of a patient lies with the doctor, not with the TGA, however some states are putting in barriers in an attempt to restrict access.

Category A - TGA Notification Only

If a medical practitioner forms the view that his or her patient fits the Category A definition (life threatening condition), the medical practitioner can supply potentially any unapproved therapeutic good to the patient without the approval of the TGA. The medical practitioner only needs to notify the TGA that they are supplying an unapproved medicine for treatment of a patient. The doctor completes the Category A form, and must send it to the TGA within 28 days.

The Category A form acts as the ‘Authority to Supply' and provides the doctor with the legal authority to obtain or supply the unapproved product.

Definition of Category A - Therapeutic Goods Regulation

> *“persons who are 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.” All other patients can access unapproved medicines under Category B which needs TGA and State approval.”*

This interpretation is very broad and would include terminal and many serious life threatening medical conditions.

Interpretation of Category A - Australian Parliament 1991

The way the definition of Category A was intended to be interpreted can be gained by reference to the discussion in the Australian Parliament in 1991 at the time the definition was being framed for inclusion in the Act. Senator Tate made the following statement:

> *"when people are confronting the certainty of death and have a terminal or life-threatening illness, special provisions clearly ought to be made to help them psychologically face that prospect by giving them assurance that virtually whatever they wish, by way of* ***administration of a drug of which they have learnt****, can be undertaken" (Hansard, Senate 12 December 1991)."*

Supply from Within Australia

If an unapproved medicine is available from within Australia, the Category A form can be sent direct to the sponsor or the pharmacy.

Importation

While patients can import cannabis medicines, it is almost impossible for most patients as it is difficult to obtain a supply from overseas, and there are even more bureaucratic processes with import and export licenses and permits.

If the cannabis products are not available in Australia, either the doctor or a pharmacist can apply to the of Drug Control (ODC) section of the TGA for an import licence, and a permit for each product. These documents are sent by post back to the doctor or pharmacist who is required to send originals by airmail to the overseas supplier for them to obtain the export approval.

Prior to 1 November 2016: Patient Access under Category A

Prior to 1 November 2016, a registered medical practitioner who formed that view that his or her patient fitted the Category A definition, could supply any unapproved therapeutic good, except for substances listed in Schedule 9 without TGA approval.

Regulation 12A - Unapproved medicines and biological - exemption in life threatening cases provided:

> (1) For the purposes of subsection 18(1) of the Act, all medicines, other than medicines of a class or kind listed in the 9th Schedule to the Poisons Standard, as in force from time to time, are exempt from the operation of Part 3-2 of the *Therapeutic Goods Act* …

Therefore prior to November 1 2016, patients could access cannabidiol (CBD) listed in Schedule 4; and nabiximols, dronabinol and nabilone listed in Schedule 8 under Category A. If a Category A patient needed access to cannabis or tetrahydrocannabinols (THC) they could only access them under Category B as they were still listed in Schedule 9.

1 November 2016: TGA Rescheduling of Cannabis and Tetrahydrocannabinols

In January 2016 the TGA commenced public consultation on the down-scheduling of cannabis and tetrahydrocannabinols (THC) from Schedule 9 to Schedule 8 in the Poisons Standard.

In February 2016, when the Narcotic Drugs Act Amendment Bill 2016 was passed in the Australian Parliament, Ms Ley announced that the Department of Health, in conjunction with the TGA, were currently well-advanced in having cannabis for medicinal purposes considered for down-scheduling to Schedule 8 of the Poisons Standard. Minister for Health Sussan Ley said:

> "This will simplify arrangements around the legal possession of medicinal cannabis products, placing them in the same category as restricted medicines such as morphine, rather than an illicit drug. This will in turn reduce any barriers to access, no matter what state a patient lives in …"

Patient and Community Expectations

Given the well known and documented delays and difficulties for patients with life threatening conditions using Category B, and due to the ongoing media reports released by the Federal Government and some of the state governments throughout 2016, there was a very strong expectation that when the down-scheduling came into effect on 1 November 2016, patients with terminal or life threatening conditions could go to their doctor, and would be afforded urgent fast-tracked access to cannabis and tetrahydrocannabinols (THC) medicines under Category A.

1 November 2016: Government's Amendments to Therapeutic Goods Regulation

On 1 November 2016, at the same time the Government down scheduled cannabis and tetrahydrocannabinols (THC) from Schedule 9 to Schedule 8, without any prior warning or public consultation, Sussan Ley also introduced the Government's discretionary amendments to the *Therapeutic Goods Regulation* that will have the adverse affect of denying patients with life threatening conditions access to any cannabis medicines under Category A as follows:

Schedule 4: Cannabidiol (CBD) – **No Access under Category A**

Schedule 8: Cannabis (dried bud for vaporising), tetrahydrocannabinols (THC), nabiximols (botanical THC and CBD), nabilone (synthetic THC) and dronabinol (also synthetic THC) – **No Access under Category A**

Please note: Prior to November 1 2016, patients could access cannabidiol (CBD) listed in Schedule 4 and nabiximols, dronabinol and nabilone listed in Schedule 8 under Category A.

Adverse Impact: Category A - Patients with Life Threatening Conditions

Instead of being afforded fast-tracked access to cannabis, tetrahydrocannabinols (THC), nabiximols, cannabidiol (CBD), nabilone and dronabinol under Category A, all patients who fit the Category A definition, will need to access all forms of cannabis medicines under Category B.

Category B can be a very costly, time consuming, convoluted and stressful process for doctors, patients and their carers. Under the Federal Government's amendments to the *Therapeutic Goods Regulation*, the doctor will need to apply for mandatory TGA approval under Category B, even if the doctor has determined that his or her patient fits the Category A definition.

The Federal Government's amendments to the *Therapeutic Goods Regulation* are discriminatory, unreasonable and disproportionate, as they deny fast tracked access to all types of cannabis medicines listed in Schedule 4 and 8 of the Poisons Standard when access to all other Schedule 4 or 8 unapproved medicines is permitted under Category A.

Furthermore, the barriers that have been put in place by the Federal Government and state governments that restrict and delay access under Category B, do not apply to any other unapproved medicine, or any Schedule 4 prescription medicine or Schedule 8 controlled substances.

Although the Federal Government's legislation to amend the *Narcotic Drugs Act* for a cultivation scheme was given bi-partisan support, and was passed unopposed, in under 24 hours, in both the House of Representatives and the Senate in February 2016, there was no mandate for the Federal Government to make these discretionary amendments to the *Therapeutic Goods Regulation* behind closed doors that will have the effect of denying patients with life threatening conditions fast-tracked access to cannabis under Category A.

The only provisions in the Narcotic Drugs Act Amendment Bill 2016 that was passed by both the House of Representatives and the Senate around patient access, were for regulations to be made for Category B, and as discussed further below, the Government's own Explanatory Memoranda to the Narcotic Drugs Act Amendment Bill states that the patient access pathways were not under review as part of the Government's proposal for a cannabis licensing scheme.

At all times throughout the TGA's down scheduling proposal for cannabis and tetrahydrocannabinols (THC), the government failed to disclose that it's policy intention was to prohibit patients with life threatening conditions from having fast-tracked access to cannabis and tetrahydrocannabinol (THC) under Category A. There was also no disclosure that doctors would need approval from the TGA under Category B as well as state approval.

Adverse Impact: Australian Cannabis Industry

The Federal Government's amendments to the *Therapeutic Goods Regulation* apply to cannabis supplied under the amendments to the *Narcotic Drugs Act* that passed in February 2016. These changes do not just apply to imports. According to the ODC, the Federal Government's policy intentions were always to prohibit patient access under Category A, and for supply to be under Category B. There was always a behind the scenes policy that cannabis medicines should only be prescribed by specialists, and not by general practitioners.

The Australian medical cannabis industry has already been put at a great disadvantage compared to overseas medical cannabis and hemp food companies. There is still no local supply available from Australian cannabis companies, as cultivation licenses have not even been issued. Only allowing patient access under Category B will have a detrimental impact on the ability of Australian companies being able to supply their medicines to patients across Australia in a timely and efficient manner.

Any unnecessary restrictions and barriers in place will only result in the black market continuing to flourish, no access to a range of products to meet the needs of all patients, and cannabis medicines from legal suppliers being more expensive for patients, and for the taxpayer if the cannabis medicines are for supply in public hospitals and other public institutions.

Personal Importation Scheme

The Government also made amendments to the *Therapeutic Goods Regulation* that will have an adverse affect on some patients who access their cannabis under the Personal Importation Scheme.

Under the Personal Importation Scheme, a person with a valid prescription from their Australian, who is travelling back into Australia from an overseas jurisdiction where they have obtained a legal supply of cannabis, the patient or their carer may import back into Australia, on their person, 3 months supply of cannabidiol (CBD) listed in Schedule 4, and/or Schedule 8 nabiximols but no more than 15 months in a 12 month period ending on the last day of importation, without the need to apply for an import licence or permit.

Adverse Impact: Personal Importation Scheme

We fully support the rights of all patients to be able to import all Schedule 4 and 8 cannabis medicines from overseas under the Personal Importation Scheme. However the Government's amendments to the *Therapeutic Goods Regulation,* in relation to the Personal Importation Scheme, will have the discriminatory and disproportionate effect of allowing any patient that can travel overseas, or their carer travelling with them, the right to import 3 months supply of Schedule 4 cannabidiol (CBD) or Schedule 8 nabiximols, however the amendments deny patients the right to import Schedule 8 cannabis or tetrahydrocannabinols (THC).

These changes are also unreasonable and disproportionate in comparison to the Federal Government's changes to Category A mentioned above, as patients with life threatening conditions, many who are in no condition to travel overseas, or cannot afford to travel overseas, are denied access to all forms of cannabis medicines under Category A.

MCAG Recommendations: Notice of Motion to Disallow

We recommend that the Federal Government's amendments to the *Therapeutic Goods Regulation* that were introduced into the House of Representatives and the Senate by the former Minister for Health, Sussan Ley on 7 November 2016 be disallowed.

Patient Access - Category A

If a doctor forms the view that his or her patient fits the Category A definition as defined in the *Therapeutic Goods Regulation,* the patient should be allowed fast tracked access to Schedule 4 cannabidiol (CBD) and Schedule 8 cannabis, tetrahydrocannabinols (THC) and nabiximols under Category A.

1. The House of Representatives and/or the Senate move a Motion to disallow the Federal Government's amendments to the *Therapeutic Goods Regulation*.

2. If this is unacceptable, in the alternative, and rather than an outright prohibition, we recommend that patients that fit the Category A criteria be allowed access to all Schedule 4 cannabidiol (CBD), and all Schedule 8 cannabis, tetrahydrocannabinols (THC) and nabiximols under Category A but with other provisions included by the way of regulations or guidelines to closely monitor access and safeguard against diversion as follows:

Cannabis supplied from within Australia:

a) The doctor is to immediately notify the TGA that they are supplying cannabis to a patient rather than the current 28 days, by sending the Category A form to the TGA with a copy of the confirmation of supply letter and current certificate of analysis from the supplier.
b) The doctor must also send a copy of the above-mentioned documents to their state or territory health department.
c) If the cannabis is dispensed from a community pharmacy, the pharmacist is to send a copy of the dispensing management plan to the state health department.

Cannabis imported from overseas:

a) If the cannabis is imported, when the doctor or pharmacist applies to the ODC for an import licence and permit (SAS Category A), the doctor is to immediately notify the TGA rather than the current 28 days, by sending a copy of the Category A form to the TGA with a copy of the confirmation of supply letter and current certificate of analysis from the overseas supplier.

b) The doctor and pharmacist must also send a copy of the above-mentioned documents to their state or territory health department with a copy of the pharmacist's dispensing management plan.
c) In the case of a child under the age of 16, the doctor includes a report from the child's treating specialist supporting the use of the cannabis treatment.

Personal Importation

1. Permit access to cannabis and tetrahydrocannabinols (THC) under the Personal Importation Scheme.

2. In the alternative, rather than prohibit access, put in place some provisions by way of regulations or guidelines to closely monitor access and safeguard against diversion, similar to the Category A notification requirements as outlined above.

Reasons to Support a Notice of Motion to Disallow

Due to the time limits for a Notice of Motion to Disallow the Federal Government's amendments to the *Therapeutic Goods Regulation,* this part of the submission mainly focuses on patient access under the SAS.

We have outlined below a number of reasons that show there is no justification for the Federal Government's amendments to the *Therapeutic Goods Regulations* to become law. Adopting our recommendations is also consistent with International Conventions, and the Federal Government's own inquiries and reports, and the intentions of Parliament when the SAS Category A was first introduced in 1991.

The Federal Government's changes to Category A are discriminatory, unreasonable, and disproportionate, when all other Schedule 4 and Schedule 8 medicines are not affected and can be accessed under Category A. Many of the unregistered medicines that Australian patients have been obtaining access to under Category A and B of the SAS have not undergone any clinical trials to evaluate safety and efficacy, and are also very addictive, and have very toxic side effects that can result in serious harm and death.

Many of the pharmaceutical drugs that are registered on the ARTG and available over the counter or as prescription 4 medicines are very addictive, and have very toxic side effects that can result in serious harm to the patient and death. There are also many drugs that are routinely prescribed off label to children that have not undergone any clinical trials in children to evaluate their safety or efficacy but are very addictive, and have very toxic side effects that can result in serious harm and death

When the Federal Government's legislation was passed unopposed in February 2016, Sussan Ley failed to disclose to the Commonwealth Parliament of Australia, that the Federal Government's policy intention was to prohibit patients with life threatening conditions from having fast-tracked access to Schedule 4 and 8 cannabis and tetrahydrocannabinols and the other cannabis medicines under the Category A process. In addition, there

was no consultation with the public, no inquiry or any scrutiny into whether there would be any adverse consequences for the patients.

Sussan Ley's Commitment to Make the SAS Work - October 2015

On 19 October 2015, the former Minister for Health, Sussan Ley announced that the Federal Government would introduce its own legislation in December 2015 to amend the *Narcotic Drugs Act* to allow the states to cultivate cannabis for medical purposes. In December 2015 the Federal Government failed to introduce its legislation. During the same speech, Sussan Ley also made a commitment to make the SAS work as effectively and as well as possible for patients who need urgent access to cannabis in the interim period. Sussan Ley:

> *"While it's legal to import supplies and provide them always of course with your doctor at the centre of your treatment we know those supplies are very hard to get and are very expensive ... the SAS that operates within the Therapeutic Goods Administration is the one there now for patients that need help urgently and I am committed to make the Special Access Scheme work as effectively and as well as possible. .... the steps we take in health must always be with the patients in mind and this is very much a measure for the patients .... their advice, their input, their passion and their advocacy has brought this to the attention of the Australian Parliament.*[9]

Sussan Ley did not introduce the Federal Government's cannabis cultivation Bill until February 2016.

Explanatory Memoranda to the Narcotic Drugs Act Amendment Bill 2016

The Federal Government's Explanatory Memoranda to the Narcotic Drugs Act Amendment Bill 2016[10] in respect to patient access under the title "Consumer access to cannabis," specifically states that the access pathways through the *Therapeutic Goods Act* were not under review as part of the Federal Government's proposal.

> "In relation to consumer access, there are a number of pathways for lawful access to cannabis for medical use through the Therapeutic Goods Act. **These are not under review as part of this proposal.** This information is provided by way of background..."

Down-Scheduling of Cannabis and Tetrahydrocannabinols

In January 2016, almost a month before the Federal Government released its legislation to the public, the TGA commenced a public consultation proposing the down-scheduling of cannabis and tetrahydrocannabinols (THC) from Schedule 9 to Schedule 8 in the Poisons Standard.

At the time Federal Government's Bill to amend the *Narcotic Drugs Act* was introduced in the Commonwealth Parliament of Australia in February 2016, Ms Ley also announced that the Department of Health, in conjunction with the TGA, was currently well advanced in having cannabis for medicinal

[9] Sussan Ley's Facebook page -19 October 2015 at https://www.facebook.com/SussanLeyMP/videos/912314365502603/

[10] See Commonwealth of Australia Explanatory Memoranda, Narcotic Drugs Act Amendment Bill 2016 at http://www.austlii.edu.au/au/legis/cth/bill_em/ndab2016250/memo_0.html.

purposes considered for down-scheduling to Schedule 8 of the Poisons Standard. Ms Ley said.

> "This will simplify arrangements around the legal possession of medicinal cannabis products, placing them in the same category as restricted medicines such as morphine, rather than an illicit drug. This will in turn reduce any barriers to access, no matter what state a patient lives in."

Government's Response: Reform of Regulation of Medicines 2016

In September 2016, and just over a month before Former Health Minister Sussan Ley introduced the Federal Government's changes to *Therapeutic Goods Regulation* to prohibit access to all forms of cannabis medicines under Category A, Minister Ley delivered the Federal Government's Response to its Review of Medicines and Medical Devices Regulation. The Federal Government accepted all of the recommendations in the report relating to access to unapproved therapeutic goods under the SAS Category A and B.[11]

In a Ministerial Statement, Ms Ley said the Federal Government had accepted the majority of the recommendations of the Review and they would bring significant benefits to consumers, the therapeutic goods industry and health professionals.

In respect to the SAS Sussan Ley also stated:

> "It will also mean that patients will gain access to essential medicines under the Special Access Scheme faster. The reforms will introduce an online system for making and tracking SAS applications. It will also increase the number of medicines subject to streamlined approval through the SAS.[12]

In respect to Category A, the Federal Government reported:

> **"the criteria and processes for Category A remain unchanged…."**[13]

In respect to Category B the Federal Government reported:

> "Access to products under the Special Access Scheme and the Authorised Prescriber Scheme will be streamlined, reducing burden for healthcare professionals and enabling ease of access to products not on the ARTG for individual patients who meet the relevant criteria. The introduction of an integrated, online system to manage SAS notifications, approvals and reporting requirements, and the development and application of transparent criteria for identifying Category B applications that could be subject to automatic approval."
>
> "A system with capacity to establish a Schedule of Category B products that are eligible for automatic approval; allow clinicians to enter a restriction code to auto-populate information relating to SAS notifications, automatic approvals and applications; and utilise smart-forms to reduce unnecessary administrative burden on clinicians and sponsors; and provide data for real-time monitoring of the SAS by the Australian NRA, to identify potential trends and abuses."[14]

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[11] Australian Government Response to the Review of Medicines and Medical Devices Regulation, Online ISBN: 978-1-76007-261-2, Publications Number: 11475. See also Therapeutic Goods Administration website at Commonwealth of Australia, Department Health website at https://www.tga.gov.au/sites/default/files/australian-government-response-mmdr-2016.pdf.

[12] Commonwealth of Australia, Ministerial Statement, The Hon. Sussan Ley, Minister for Health and Aged Care, Minister for Sport, 15 September 2016, Department Health website at http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2016-ley064.htm?OpenDocument&yr=2016&mth=09.

[13] See Recommendation Twenty-Four and Government response at page 23.

[14] See Recommendations Twenty-Five and Six and the Government's responses at page 24.

Fast Tracked Access to Cancer Drugs and the Export Market

The review was clearly undertaken to support fast tracked access to pharmaceutical cancer drugs and for the export market. In her Ministerial Statement, the former Minister for Health, Sussan Ley also stated:

> "Provisional approvals will also be available which could result in certain life-saving medicines such as new cancer drugs coming to market two years sooner… Bringing medicines onto the Australian market quicker will be achieved, in part, by greater use of assessment of medicines by comparable overseas regulators like the US FDA and the European Medicines Agency… performing assessments is critical to the success of Australian manufacturers in exporting therapeutic goods, particularly to Asian markets but will also increase use of overseas assessments with comparable regulators such as the US and European Union…"

Australian Sovereignty and Regulation of Medicines

While the Federal Government maintains that Australia must keep tight controls on the use of cannabis because of its international obligations under the Single Convention on Narcotic Drugs 1961, in the Federal Government's Response to its Review of Medicines and Medical Devices Regulation, the Federal Government reported that the Australian Government, as a sovereign entity, must maintain sovereignty of decision-making and the capacity to undertake assessments of therapeutic goods for safety, quality and efficacy. In recognising the Australian Government, as a sovereign entity, the Federal Government reported:

> "… maintenance of Australia's capacity to undertake assessments of therapeutic goods, and sovereignty of decision-making is an important assurance to consumers, and underlines Australia's strong reputation as a regulator of therapeutic goods, and also noted the strong reputation of the Therapeutic Goods Administration (TGA)."

Single Convention on Narcotic Drugs 1961: Regulation of Cannabis

The Federal Government has stated that its power to control cannabis under federal law comes from the Australian Government's power to invoke Australia's international obligations under the Single Convention.

The Single Convention on Narcotic Drugs 1961 (the Single Convention) is attached as Schedule 1 to the Commonwealth *Narcotic Drugs Act.* The Preamble to the Single Convention provides that signatories to the Single Convention concerned with the health and welfare of mankind:

> "recognize that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering, and ***must*** (emphasis added) ensure that adequate provisions are made available for medical and scientific use.[4]

The Australian Government has failed its obligations under international law, as the Single Convention clearly sets out, that signatories **must** provide for 'narcotic' medicines to be **available for medical** and scientific use; and provide treatment for drug dependent people; and use law enforcement measures to combat the illegal trafficking in narcotic cannabis and other narcotics.

International Narcotic Control Board: Australia's Reporting Obligations

By adopting our recommendations as above, and allowing access to cannabis, tetrahydrocannabinols (THC), and cannabidiol (CBD) under Category A, the Australian Government can still fulfil its reporting obligations to the INCB as set out under the Single Convention.

The TGA will have a copy of the Category A form with details of the doctor, supplier, the form of cannabis medicine, dosage, and total quantity of cannabis medicine. In addition, if the cannabis is imported, the ODC of the TGA will also have a copy of these documents for the record.

State health departments if doctors send them a copy of the Category A form and will also receive records from pharmacists, as they also need to keep full records of medicines dispensed and their stock on hand, and send monthly reports to state health departments.

Risk of Diversion

As mentioned above the TGA, ODC and state health departments will have access to adequate and sufficient information and records and will be able to track any possible diversion or overprescribing by doctors. In addition the TGA and state health have monitoring programs and systems in place already.

There is no justification or evidence to support the Federal Government's prohibition on access to cannabis, tetrahydrocannabinols (THC), cannabidiol (CBD), or nabiximols under Category A. The Federal Government's amendments are unreasonable, discriminatory and disproportionate when access to all other Schedule 4 and Schedule 8 unapproved medicines are permitted under Category A.

Parliamentary Inquiry into the TGA: Baume Report 1991

In 1991, the then Minister for Health, commissioned Professor Peter Baume to conduct an inquiry to seek improvements in Australia's drug evaluation system operating within the TGA. The main theme of Professor Baume's report "A question of balance: report on the future of drug evaluation in Australia," was the need to ensure the timely availability of drugs to the public.

In his report, Baume was critical of the TGA's mission statement, which at the time only referred to the quality, safety and efficacy of therapeutic goods but failed to mention the crucial aspect of timeliness at all.

The Federal Government, at the time, accepted all of the 164 recommendations posed by Professor Baume. The report led to a number of amendments to the *Therapeutic Goods Act* including the inclusion of timely access, the SAS with Category A for patients with life threatening conditions who need fast tracked access to unapproved medicines as a TGA notification only pathway, and Category B for all other patients which requires TGA approval.

Intentions of Commonwealth Parliament of Australia 1991

Adopting our recommendations is also consistent with the intentions of the Commonwealth Parliament of Australia when timely access, and Category A and B of the SAS were first introduced into the *Therapeutic Goods Act 1989* in 1991.

The Australian Parliament's intentions in 1991 were clear - to give the TGA a clear statutory direction, and that timeliness was to be one of their principal aims.[15]

The two separate categories under the SAS were introduced to replace the Individual Unit Program (IUP) because it was inefficient and time consuming and was similar to Category B works now, as doctors then needed to wait for TGA approval for all patients.

Category A was introduced to rectify the imbalance between patients who have the right to urgent access unapproved medicines and who do not have the luxury of waiting for the TGA to give their doctor approval. Category B was introduced for patients with chronic and disabling medical conditions that are not life threatening but who still have the right to access unapproved medicines.

Category A was intended to provide greater access to unapproved medicines by persons with a terminal or life threatening illness on the condition the patient must personally accept the greater risks involved. All patients using the SAS must give their written informed consent to the doctor, and accept all liability for any adverse affects from using the unapproved medicines.

Following are some extracts from Senator Lee's speech in 1991 on the inclusion of the **"timely"** access to medicines in the *Therapeutic Goods Act;* and the use of unapproved medicines under the SAS, and the doctor patient relationship which are very relevant to the issues with patient access to cannabis today.

Senator Lee's speech on the ongoing problems with the TGA and the need for the inclusion of timely availability in the *Therapeutic Goods Act*:

> "Professor Baume's report was not the first time these issues have been canvassed, as has already been noted in this chamber today; indeed, it was the sixth, seventh or eighth time that our drug regulation system has been looked at. However, Professor Baume considered this tension between safety and availability very carefully and he pointed out the need for a balance between these two concerns.
>
> He also highlighted the fact that this is not really covered anywhere in the existing legislation—the Therapeutic Goods Act. He saw that omission as having a significant impact on the performance of the TGA and the perception it has of itself. In his report summary he was critical of the TGA's mission statement which refers only to the quality, safety and efficacy of therapeutic goods and fails to mention the crucial aspect of timeliness at all.

[15] See the second reading speeches, amendments to the *Therapeutic Goods Act* 1989, 1991, Commonwealth Parliament of Australia website at http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;db=CHAMBER;id=chamber%2Fhansards%2F1991-12-12%2F0030;query=Id%3A%22chamber%2Fhansards%2F1991-12-12%2F0031%22

> The present object of the TGA would be served best if no new drugs were made available *ever*, for only then could one be completely sure that Australians would suffer no untoward effects of new drugs.
>
> This Bill attempts to rectify the imbalance in the Therapeutic Goods Act, giving our drug evaluators a clear statutory direction that timeliness is now to be one of their principal aims."

Almost twenty years on after Senator Lee made his speech in 1991 in Senate of the Commonwealth Parliament of Australia about the issues faced by patients with life threatening illnesses, and the delays and difficulties that they were experiencing when trying to access unapproved medicines through the TGA then, are the same issues that patients with life threatening conditions who need cannabis medicines are facing today with the TGA.

> "Life-threatening illnesses for which inadequate therapies exist deserve urgent attention by society. Cancer and AIDS qualify eminently for this designation. Patients suffering from these diseases cannot afford the luxury of waiting for drug development and regulation to move as slowly as they usually do towards ultimate regulatory approval and marketing. For cancer and AIDS patients time is running out and they are understandably impatient with delays in obtaining the pharmacotherapy, which represents their only hope.
>
> When, as has been occurring in this country, we combine delays in marketing approval with a complex and unwieldy individual access program, it is not hard to see why people with a life threatening illness have become increasingly frustrated and annoyed by the hoops that they have to jump through and the hurdles that they have to climb over in order to gain the drugs that they urgently want.
>
> Over the years many people with life threatening illnesses have travelled overseas to attempt to access these drugs. They have secretly imported some restrictive products or unapproved drugs into the country, and in this past year we have seen the AIDS Council of New South Wales set up a program to assist people to import anti-HIV drugs via a quite complex overseas network, including a buyers club in America. I believe it is neither fair nor desirable that seriously ill people should have to go to such lengths, should have to go through such trauma and should be put to such expense because the official system is not properly catering for their needs."

Senator Lee's speech on the limitations of the IPU and the introduction of the SAS and the inclusion of fast tracked access under Category A:

> "Recognising the limitations of the IPU system, Professor Baume recommended that a new scheme for special access to unapproved drugs be established, and this Bill before us sets up some of the legislative framework for such a scheme. Among other things, the Bill contains provision for the secretary to authorise specific medical practitioners to directly supply unapproved drugs to patients who are seriously ill with life threatening illnesses.
>
> *This makes it clear that, subject to the authorisation process, the decision about the use of the unapproved product and its associated risks is the province of the patient and his or her doctor."*

Professor Baume's report shows that the TGA have a very long history of failing patients who have life threatening conditions, and also patients with chronic and disabling conditions who also have a legal right to timely access to unapproved medicine under the exemption schemes in the *Therapeutic Goods Act.*

Lack of Public Consultation

At no time did the Federal Government disclose to the public that its policy intentions were to prohibit access to cannabis under Category A. The Federal Government failed to consult with patient advocacy groups about the changes, and did not even notify the patients who are already accessing cannabis through the SAS.

From October 2015 when Sussan Ley first announced that the Federal Government would be introducing its own legislation instead of supporting Senator Di Natali's Bill for an independent regulator outside of the TGA, up until when the Federal Government introduced its proposal to down-schedule cannabis and tetrahydrocannabinols in January 2016, and its own Bill to amend the *Narcotic Drugs Act* in February 2016 there was no public consultation with the patients who were using the SAS or any patient advocacy groups.

From October 2015 up until when the Federal Government introduced its amendments to the *Therapeutic Goods Regulation* on 7 November 2016, there was no consultation with the patients who were using the SAS or any patient advocacy groups.

Bill Turner's Speech UIC Symposium May 2016

We reject the Federal Government's proposition that the public were informed about the Federal Government's intentions not to use Category A, and that its intentions were always for access under Category B. Bill Turner's fleeting reference to Category B, in his speech at the UIC symposium in May 2016, that he also pointed out is on the UIC website, does not constitute public consultation or consultation with patient advocacy groups. In any case his speech was delivered months before the Federal Government and TGA handed down its final decision on the down-scheduling.

Government Websites

Prior to the Federal Government's amendments to the *Therapeutic Goods Regulation,* the ODC and TGA websites made no reference about the government's intentions to stop patient access under Category A. After the amendments were made, on or about 31 October 2016, the TGA's medical cannabis page was updated to include a very obscure reference to doctors that access was not available under Category A. None of the pages with general information about patient access to unapproved medicines, or the SAS have been updated on the TGA's website.

Health Rights and Liberties of the Patient

One of the most important rights and freedoms that patients have when it comes to their health is the fundamental right to choose their own medical care and treatment for any condition representing a harm or danger to their health or quality of life. This concept has been widely adopted by the courts in Australia and overseas jurisdictions.

In *Rogers and Whitaker*[16] the High Court of Australia stated:

> "the courts have adopted in several cases[17] the principle that while evidence of medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care ***after giving weight to the paramount consideration that a person is entitled to make his own decisions about his life***."[18]

In respect to the use of cannabis, it is now widely recognised and accepted in overseas medical cannabis programs, that it is the patient, in consultation with his or her doctor, who are best placed to determine the individual needs of the patient, not the Federal Government or state government, or an advisory panel, all of whom are so far removed from the patient's care and treatment.

The Federal Government's amendments breach human rights and trespass unduly on the personal rights and liberties of patients who have life threatening medical conditions, and unduly make the rights and liberties of all patients with life threatening medical conditions dependent upon administrative decisions, which are not subject to review of their merits by a judicial or other independent tribunal.

In the ultimate, it should be the patient or carer in consultation with his or her own medical practitioner who makes the final decision on whether the patient should use cannabis medicines, and in which form. The Commonwealth and state governments should not come between the doctor-patient relationship by putting in place so many barriers that make access almost impossible to achieve.

Discrimination

The Federal Government's amendments to the *Therapeutic Goods Regulation* are unreasonable, and discriminate against patients who use cannabis for medical purposes. Cannabis medicines are the ONLY Schedule 4 and Schedule 8 therapeutic goods that patients with life threatening conditions are not permitted access to using the Category A notification only pathway.

2. Patient Access Issues Category B: TGA and State Approval

Even before the rescheduling came into effect, some of the states had already adopted the Federal Government's recommendation into state laws and classified cannabis in state health legislation as a Schedule 8 controlled drug of addiction. The states have also put in extra controls and barriers to access cannabis and tetrahydrocannabinols (THC) that do not apply to any other Schedule 8 substance, including toxic drugs of addiction like morphine and methadone.

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[16] *Rogers and Whitaker* (1992) 175 CLR 479 at p 487.

[17] See for example *Albrighton v. Royal Prince Alfred Hospital* (1980) 2 NSWLR at pp 562-563; *F v. R.* (1983) 33 SASR 189 at pp 196, 200,202, 205; *Battersby v. Tottman* (1985) 37 SASR at pp 527, 534, 539-540; *E v. Australian Red Cross* (1991) 99 ALR at pp 648-650.

[18] *F v R.* (1983) 33 SASR at p 193.

The states are also treating patients as if they are drug dependent, and regulating cannabis how the methadone program is managed. For example, in Queensland, doctors do not need State approval to treat patients with any other Schedule 8 controlled substance unless the doctor determines that the patient is drug dependent.

However when using cannabis, fter a doctor obtains the mandatory Category B approval from the TGA, the doctor then needs to apply for state approval. A decision can take up to 90 days as the state approval process duplicates the TGA process and the case can also be referred to an expert panel that only meets once a month. If the doctor obtains approval, there are then further delays of up to another 90 days for the pharmacist to obtain approval to obtain and dispense the cannabis.

Some states for example NSW and Victoria have restricted prescribing to specialists only. Some states also have age and product restrictions or access is restricted to TGA approved authorised prescribers in which doctors still need state approval. Although authorised prescribers only need TGA and state approval once, they are restricted to treating specified patients with certain conditions, and with a specified product. They are also responsible for ensuring a consistent supply of the product to treat their patients.

The state process for doctors is a time consuming and unnecessary duplication of the TGA process. It can take a doctor up to 3 months to obtain state approval as applications can be referred to an expert panel for review. This is not good enough for any patient. The state process needs to be streamlined for doctors as the TGA Category B approval process is already time consuming.

MCAG Recommendations: Category B

As mentioned above all patients with life threatening conditions should have to access to their cannabis under the Category A - TGA notification only process.

We also believe that the concept behind the Category A - notification only process should be afforded to all patients accessing cannabis as an unapproved medicine. However we acknowledge that it may take some time for this to be fully implemented.

As an interim measure, the Category B process must be streamlined to make access achievable for patients with chronic and disabling conditions that are not life threatening. The only acceptable way to streamline and make the Category B process workable for doctors and patients is to remove the requirement for doctors to obtain state approval and replace it with a state notification process.

Our recommendations are as follows:

1. A doctor with Category B approval from the TGA should only need to notify his or her relevant state health department they are treating a patient with cannabis medicines by sending a copy of the Category B approval letter, and certificate of analysis to his or her state health department within 7 days.

It is unreasonable to expect doctors to obtain approvals and report back to 2 separate government departments, one under federal jurisdiction and the other under state jurisdiction, and unreasonable for any patient with a chronic and disabling medical condition to have to wait up to 6 months or longer before they can access their medicine. The Category B process is explained in more detail below.

3. Patient Access Issues: Authorised Prescriber Scheme

Currently under this TGA scheme doctors can apply to the TGA to be approved to treat several patients without the need to obtain TGA approval each time. However doctors also need to obtain a one off ethics approval from a research committee, and a one off state approval.

Although a doctor only needs a one off approval from the TGA, ethics committee and the state, and can also choose to treat as many patients as they wish, under their approval they are restricted to treating a class of patients with the same specified medical condition, using the same specified cannabis medicine.

The doctor is also responsible for organising and ensuring that that there is an ongoing and adequate supply of the medicine to treat all of his or her patients.

Another issue with this scheme is that the TGA does not restrict authorised prescribers to only specialists. GP's can also apply to the TGA to be authorised prescribers, however the states have introduced conflicting laws that only apply to cannabis medicines, and that at a state level restrict TGA approved authorised prescribers to only certain specialists. For example in Queensland, only specialists in palliative care, oncology and childhood epilepsy can apply for the state approval that is needed for a doctor to become an authorised prescriber.

It would be more efficient for doctors who are interested in treating their patients with cannabis to become authorised prescribers. For this to occur the approval process needs to be streamlined.

To attract doctors to be cannabis prescribers, there needs to be Federal Government grants and training and support made available to the doctors who are interested in treating their patients with cannabis medicines, as doctors have difficulty now obtaining approval and supply for 1 patient at a time under the SAS.

The TGA and state health also need to make a list of authorised cannabis prescribers available to the public.

MCAG Recommendations - Authorised Prescriber Scheme

Our recommendations are as follows:

1. Either a GP or specialist can apply to the TGA to be an authorised prescriber.

2. Doctors who have obtained TGA approval to be an authorised prescriber do not need state approval, and only need to notify the state they are treating patients with cannabis.

3. Authorised prescribers are not restricted to treating patients with the same medical condition, and are not restricted to using the same cannabis medicine, and can treat a patient using multiple cannabis medicines if required.

4. Doctors who have treated 3 or more patients with cannabis medicines under the Category A pathway can apply to the TGA for automatic approval as an authorised prescriber, without the need for ethics approval and approval from the state government.

5. Doctors who have obtained TGA approval under Category B (case by case basis) on 2 or more occasions can apply to the TGA for automatic approval as an authorised prescriber.

6. TGA make available to the public, a list of all TGA approved authorised prescribers.

4. Unjust State and Territory Criminal Laws

All across Australia patient advocacy groups have been calling for an end to the state criminal drug laws that put patients and their carers who are cultivating their own cannabis or obtaining it from the black market at risk of being arrested and charged with serious criminal offences, and their medicine confiscated by police. Parents also have the added risk of the intervention of child services.

Due to constitutional limitations under Australia's federated system of government, the Commonwealth Parliament of Australia cannot make legislation for cannabis that is regulated under state criminal and health laws.

However, the Commonwealth Parliament can move a motion for the Federal Minister for Health to down-schedule the cannabis and tetrahydrocannabinols (THC) that is currently grown and used by patients, but puts them at risk of being arrested and charged with criminal offences under state laws from Schedule 9 in the Commonwealth Poisons Standard to Schedule 1, as a recommendation for states and territories adopt into state law.

We are calling members of the Commonwealth Parliament of Australia to support patients who need an alternative medical cannabis programs under state law to the Federal Government's commercial TGA scheme. Patients and carers who grow their own cannabis "out of necessity" need approvals under state health laws that will exempt them from criminal charges under state criminal laws. Patients also need approvals for genuine compassionate suppliers, that are registered as not for profit incorporated associations.

MCAG Recommendations - Unjust State and Territory Criminal Laws

We ask the Commonwealth Parliament of Australia to consider the following recommendations:

1. Move a Motion to recommend that the Minister for Health immediately down-schedule cannabis and tetrahydrocannabinols (THC) from Schedule 9 in the Poisons Standard to Schedule 1 (currently empty) when used for medical purposes in accordance with state or territory law.

2. Move a Motion to recommend that the states and territories introduce their own legislation for an alternative cannabis scheme to regulate the cultivation, manufacture, possession, supply, dispensing, and use of cannabis and tetrahydrocannabinols (THC) listed in Schedule 1 for residents in their own jurisdictions with provisions for a statewide photo ID register for patients, carers, nominated carers and not for profit incorporated associations or cooperatives with guidelines to prevent diversion as follows:

    a. A registered medical practitioner (GP or specialist) has provided a letter of recommendation that the patient may benefit from using cannabis or tetrahydrocannabinols (THC).

    b. The patient or a legal guardian has been provided with information that the cannabis is an unregistered medicine and not approved by the TGA or state health authority, and the patient or legal guardian has given their full written informed consent and accepts full responsibility for any adverse outcomes of using the unregistered cannabis or tetrahydrocannabinols (THC).

    c. The doctor has notified the relevant state or territory health department they have recommended its use, and the patient is registered on a statewide photo ID register, and has provided proof of residency, and photo identification.

    d. A patient can cultivate up to 6 cannabis plants at any given time, if a registered medical practitioner (general practitioner or specialist) has provided a recommendation as above as long as they are not selling it or giving it away, and it is kept out of the reach of children. If a patient requires more than 6 cannabis plants, they can apply to their state health department stating the reasons why they need to cultivate more than 6 plants.

e. Cannabis or tetrahydrocannabinols (THC) supplied by a not for profit, the cannabis must be cultivated in accordance with good agriculture practices, and processed, packaged and labelled in accordance with state health food standards.

f. Each state and territory is to include provisions for reciprocal rights for patients traveling interstate.

g. The states and territories are to provide reports to the Commonwealth on the amount of cannabis being cultivated within their jurisdiction to report to the International Narcotics Control Board (INCB).

h. The states can collect licence, registration and other fees from not for profit incorporated associations, and smaller companies only supplying cannabis within Queensland.

5. Medical Cannabis and Hemp Food Industry

As mentioned above our main priority and focus for our group and with this submission is around patient access issues, and while we acknowledge that industry is desperately needed, there also needs to be alternative models that provide for timely, affordable and compassionate supply from not for profits or patient collectives, and provisions for patients who want to grow their own cannabis even when industry is established.

From the outset, the Federal Government's objectives and policy intentions behind the legislation were seriously flawed and misled the public. The Federal Government's objectives were not intended to facilitate or guarantee a supply of cannabis for retail supply to the public in the short or medium term (5 - 10 years).

The Federal Government took advantage of the support that had been given to Senator Natali's Bill's for an independent cannabis regulator to be established outside of the TGA, and instead the Federal Government's legislation keeps the full control of cannabis under the TGA/FDA pharmaceutical and clinical trial model, and under outdated schedules, which are unsuitable for cannabis. They also rely on the states to adopt them into law which means further holds up waiting on the states to legislate, and the states adding another layer of bureaucracy at every step, from seed to sale.

As discussed further below, medical cannabis program overseas have regulated cannabis as a unapproved/unregistered medicine that is supplied to patients upon a doctor's recommendation without making patients wait on research trials. CBD is not sold as a prescription medicine but is sold over the counter as a food supplement.

The TGA has ignored the abundance of research that has been carried out overseas, and instead has implemented legislation that holds up immediate supply for the benefit of companies and researchers involved in expensive

research trials with the long-term goal of registration of commercially patented products on the ARTG, that will give the company exclusive marketing approval rights, and eligibility for their product to be subsidised on the tax payer funded PBS.

The TGA cannot compel an overseas or an Australian company to register their products on the ARTG when trials are completed, and even when products are registered, the TGA cannot compel a company to apply for registration for their product to be subsidised under the PBS, or keep a stock of their products in Australia so patients don't have to import.

The Federal Government's cannabis legislation has failed patients and the community and will continue to be a failure until the Federal Government streamlines processes or the states introduce an alternative model.

Restrictions and barriers are only serving to stifle industry and delay supply indefinitely. Supply from industry from seed through to patient access needs to work effectively and needs to ensure that there is a timely, accessible, adequate and ongoing supply of cannabis medicines that are affordable and that will meet the needs of all patients Australia wide.

The cannabis industry does not have years to wait for a review of the legislation. More importantly, patients don't have the luxury of time on their side, and should not have to wait weeks or months for access, let alone 5 - 20 years waiting on state governments to conduct expensive research trials on behalf of large overseas companies, and using imported cannabis in the hope that if viable, these companies will apply to the TGA for marketing approval and product registration on the Australian Register of Therapeutic Goods (ARTG).

Patients have already been through this with GW Pharmaceuticals, a UK company who used its research trials from overseas to register its Schedule 8 nabiximols product, marketed as Sativex, on the ARTG in 2010, but the TGA rejected an application for the PBS in 2013 for subsidised supply only to MS patients. Sativex is expensive and can cost up to $1,500 a month, and still needs to be imported through the SAS or by an authorised prescriber, as GW Pharmaceutical's Australian sponsor does not have stock on hand available for ready supply in Australia.

Patients need timely access, not ongoing bureaucratic barriers and delays.

So while we do not profess to have solutions for all of the issues around the cannabis-licensing scheme, and have only touched on some of the issues, we believe that our recommendations are sensible, and will go towards improving the currently unacceptable and unworkable situation for industry intending to supply medicines under the current federal cannabis licencing scheme.

MCAG Recommendations - Industry

Our recommendations that may go towards resolving some of the issues for industry are as follows:

1. Interim Measures - Federal Cultivation and Manufacturing Licences

The ODC and TGA are to fast track approvals for licenses for companies who are ready to commence cultivation and manufacture for immediate supply for patients to access as an “unapproved medicine,” and in the interim use the TGA patient access pathways, but only according to our recommendations above for fast tracked patient access through SAS Category A and B, and authorised prescribers.

2. Cannabis and Tetrahydrocannabinols

Move a Motion for the Minister of Health to down-schedule cannabis and tetrahydrocannabinols from Schedule 8 to either Schedule 4 prescription medicine, or to Schedule 5 to be manufactured under complimentary medicines standards for retail sale and supply over the counter in health food shops or pharmacies.

Please also see our recommendations for an alternative model instead of unjust state and territory criminal laws.

3. Hemp Seed and CBD Hemp Oil Products

The issue with hemp seed products and cannabidiol (CBD) hemp oil products from the low THC or no THC industrial cannabis plant, that is cultivated under state hemp licences needs to be resolved as a matter of urgency. Australia is the only country in the world that does not allow hemp seed products to be sold for human use as a food supplement, and will soon be the only country that does not allow CBD hemp oil products as food supplements.

Overseas hemp seed products have been available and sold over the counter and online as food supplements for over a decade. In some countries hemp seed food products have always been available. Similarly overseas, CBD hemp oil products from the industrial cannabis plant are available for sale over the counter and online, without the need for a prescription.

Our recommendations are as follows:

a) The Commonwealth Department of Health approves the current application for hemp seed products for human use, for sale and supply online, and in health foods stores or pharmacies.

b) The Minister for Health down-schedule cannabidiol (CBD) from Schedule 4 to Schedule 5 in the Poisons Standard, when the cannabis products have been manufactured from the industrial cannabis plant under a federal licence, or an existing industrial hemp cultivation and manufacture licence that has been issued under state laws.

c) The TGA allow the manufacture of CDB hemp oil products under complimentary medicines standards or food standards for retail sale and supply over the counter in health food shops or pharmacies.

d) All states and territories amend industrial hemp cannabis laws if necessary, and allow small business and farmers to cultivate the industrial cannabis plant for manufacture into hemp seed and CBD hemp oil products for human use under state health food standards.

Companies that can afford to spend 5, 10 or 20 years and tens of millions of dollars conducting research trials with the aim of developing a cannabidiol (CBD) product as a Schedule 4 prescription medicine, under a TGA pharmaceutical manufacturing licence with the goal of product registration on the ARTG, and listing on the PBS can still do so if they so desire.

4. Independent Review or Inquiry

The Federal Government and state governments have taken advantage of the complexity of cannabis, and cannabis reform being legislated under a federated system of government, and have created an illusion of reform, and in the process of so called "historic" reform have made it look like something great is being done when in fact, in the process, patients have been stripped of their human and health rights, but there is still no legal supply, and the patients and the cannabis that patients are actually using is still criminalised under unjust state laws.

In February 2016 the Federal Government released its cannabis Bill however only 2 weeks later it passed unopposed, in both the House of Representatives and the Senate in just under 24 hours. There was no public consultation or scrutiny into whether there would be any adverse consequences for patients or industry.

On 23 February 2016, in the House of Representatives, Labor supported the Bill but had called for a short inquiry to be held in the Senate. However overnight, and after midnight telephone calls between the Federal Government, and 1 member of the public, the Greens were persuaded to give their support in the Senate and to not oppose the Bill, on the proviso that an independent Advisory Council would be established to oversee and guide the writing of the regulations for the licences.

On 24 February 2016, in a Ministerial Statement, Ms Ley announced:

> "… an independent Advisory Committee would be established to oversee the next stage of the rollout of the national regulator now legislation has passed."[19]

The regulations under the *Narcotic Drugs Act,* to facilitate the licenses were released in October 2016. However, the appointment of the Chair on the Advisory Council did not occur until late December 2016. There was no prior public notice or invitation to the public about this appointment, and no consultation about the appointment of other members of the council.

[19] Ministerial Statement, Hon. Sussan Ley, Minister for Health and Aged Care, and Minister for Sports, Department of Health website at http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2016-ley013.htm?OpenDocument&yr=2016&mth=02

Apart from large corporations with a pharmaceutical and cannabidiol (CBD) agenda, and 1 or 2 individuals (with no or very little experience in cannabis, policy making or law) have been the only one consulted, while small industry, genuine compassionate suppliers and patient advocacy groups with qualified patient advocates with extensive experience in cannabis and the law were excluded from the decision making process.

Patients and parents desperate to access cannabis medicines legally have been deceived. The black market continues to flourish while patients and carers right across Australia are suffering pain and death needlessly. Their privacy, health and human rights have been breached and trampled over in the process. The legislation that has been passed by the Federal Government and some of the state governments over the past 12 months has been a sham and has failed patients miserably.

No one has the right to trample over another person's human and health rights or come between the patient and doctor relationship. Good policy and law reform around patient access and industry will only be achieved with input from industry experts and qualified and impartial patient advocates who understand cannabis, and the complex legal issues around cannabis law reform, and who will represent and advocate for the rights of all patients.

We recommend the following:

a. An immediate and transparent independent review or inquiry into the Federal Government's legislation, and its interaction with legislation introduced by state governments, and a review on how patient access and industry should be regulated long term under federal and state and territory laws.

b. Immediate appointment on the Advisory Council of independent and qualified patient advocates, who have no conflict of interests, and the inclusion of patient advocates in all decision making process that may impact on product supply and patient access.

Conclusion

In the interests of Australian patients with life threatening conditions who need to have fast-tracked access to cannabis, tetrahydrocannabinols (THC) and cannabidiol (CBD), and nabiximols, we recommend that all Members of the Australian Parliament support a Motion to Disallow the Federal Government's proposed amendments to the *Therapeutic Goods Regulation.*

It is unconscionable, that just when patients with life threatening conditions were expecting to be able to have fast-tracked access under Category A, Sussan Ley introduced the Federal Government's discretionary amendments to the *Therapeutic Goods Regulation* that has the effect of denying them access to any form of cannabis medicines under Category A, whether it's imported or whether it comes from an Australian supplier.

It is unreasonable to make any patient go through the TGA and state bureaucratic processes under Category B, but to deny patients with life threatening conditions their right to access their medicines in a timely manner under Category A, and instead, make them wait 6 months or even longer under the Category B process is just unconscionable.

It is also unreasonable and discriminatory to allow any patient that can travel overseas, or their carer travelling with them, the right to import 3 months supply of Schedule 4 CBD or Schedule 8 nabiximols, but as mentioned above not allow patients with life threatening conditions, many who are in no condition to travel overseas, or cannot afford to travel overseas, to access any form of cannabis medicines under Category A.

It is unconscionable and unacceptable, that the only response from the Prime Minister to patients and carers calling for these issues to be resolved, is that there will be no amnesty; import your cannabis but your doctor needs TGA and state approval under bureaucratic processes that can take longer than 6 months, and all patients, carers and compassionate suppliers still remain criminals, and at risk of being arrested, charged, prosecuted and imprisoned under unjust state laws.

It is unacceptable that, more than 2 years on from when Mike Baird announced the NSW research trials that have been beset with problems, and 2 years on from when Senator Di Natali introduced his Cannabis Bill, and 12 months on from when the Australian Parliament passed, unopposed, the Federal Government's cannabis scheme.

It is unacceptable there is still no legal supply of cannabis, tetrahydrocannabinols (THC), and not even a supply of cannabidiol (CBD) from the hemp plant, available in Australia, and only 40 children in all of Australia have access to imported cannabidiol (CBD), while 30 children accepted for the cannabidiol (CBD) trial in Queensland are still waiting, and the other research trials also using imported cannabis haven't commenced.

The Government Victoria was trying to grow its own cannabis for a trial for children in 2017 but that has had issues. Patients and children in other states are still waiting on their governments to change laws. No states have addressed the injustice of state criminals laws or made changes to cater for patients growing their own cannabis.

From the outset the policy objectives behind the Federal Government's commercial cultivation and manufacturing licensing scheme were not going to deliver an immediate supply of cannabis in the short or medium term, and were not going to address the needs of patients and carers who are at risk of being charged under unjust state criminal laws.

The legislation was drafted for an improper purpose, and in a way that ensured that any cannabis supplied for actual use, would be delayed for as long as possible for the benefit of multi-million dollar state government funded and private research trials that are using cannabis that is being imported from large overseas pharmaceutical companies and large overseas commercial medical cannabis companies.

The Federal Government stated that it is not expecting a large industry "***in the short to medium term***" and that by adopting this model it will not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG) in the short or medium term, but will facilitate clinical trials that may support such a registration in the future.

The licensing scheme is going at a snail's pace. The ODC have said recently that they are only just starting to assess 3 licence applications. It has also been indicated by the Federal Government, and state governments that more state and territory laws will need to be amended before any successful applicant can commence cultivation and the manufacture of cannabis products.

Despite the tens of millions of dollars that have already been invested in the cannabis industry in Australia from the Federal and state governments and the private sector, with a great deal of it spent on inquiries, drafting legislation, media campaigns, lawyers, all that the Federal Government and some of the state governments, and many companies have done, or plan to do, is import expensive cannabis products from overseas for limited research places in restrictive trials while patients have been left with access to only imports through the SAS which does not work for patients.

While access is delayed for researchers and corporations to prosper, the patients and their carers are treated as criminals, and expected to wait 10 - 20 years for expensive patented single molecule products that do not work as effectively as whole plant cannabis, and told to import it themselves, at their own expense, through bureaucratic processes imposed on them, and their doctor and pharmacist by the Federal Government and their state government's health department.

The Federal Government has conceded that they cannot guarantee the availability of any commercial products in the short or medium term, 5 -10 years, and long term. Even with research trials there is no guarantee that companies will register their products on the ARTG, or be eligible for PBS funding.

Sativex is the only registered cannabis medicine on the ARTG. Cannabis can never be a pharmaceutical agent in the usual sense for medical prescription, as it contains a variety of components of variable potency and actions, depending on its origin, preparation and route of administration.

Consequently, cannabis has variable effects in individuals. It will not be possible to determine a universally safe dosage of cannabis for individuals based on a clinical trial.

Overseas, Israel, the Netherlands, Canada, and over 25 states in the United States commenced their medical cannabis programs with timely access to only dried cannabis as an "unapproved" medicine upon the recommendation of a doctor instead of a prescription.

Doctors overseas only need to notify or obtain approval from a national regulator, or in the United States, approval comes from a state health department. Doctors overseas don't need to go through unnecessary bureaucratic processes, and be made to obtain approval from the national health regulator and a state health department.

Once approved, a doctor can tailor treatment to meet the individual medical needs of his or her patient, and also has the flexibility to adjust the dosage, or add or change the product if required, and unlike in Australia, doctors overseas do not need to obtain approval from the authorising agency each time.

This is how patient access to unapproved cannabis medicines should work, and how the Commonwealth Parliament of Australia in 1991 intended it to work for access to any unapproved medicine.

It is unconscionable that it appears that the Federal Government and state governments have colluded to put in as many barriers as possible to make access almost impossible for most patients to achieve, regardless of whether it's imported from overseas or whether it comes from an Australian supplier, and have also colluded to keep the status quo in place in respect to the unjust criminal laws.

Hundreds of thousands, or even more patients across Australia, who are already using cannabis for medical purposes, and their carers, and potentially hundreds of thousands more patients who could benefit from using cannabis have been left behind or left out altogether under the legislation that has been introduced by the Federal Government and some of the state governments.

There is already an abundance of research studies from overseas that show cannabis is safe and effective for a wide range of conditions and symptoms.

Patients in other overseas medical cannabis programs have not had their national or state governments make them wait for 10 to 20 years for private investors, or for the government to conduct research trials for the benefit of researchers and overseas corporations who are seeking to patent and register single molecule cannabis products.

Even in the United States, the FDA has supplied cannabis cigarettes to patients from the 1970's, and now over half the states have medical cannabis programs that allow access and don't make patients wait on trials.

As mentioned above, it is unconscionable that the Federal Government is blocking fast-tracked access under Category A, but also unconscionable, that the Federal Government and state governments have also shown a total lack of regard for the hundreds of thousands of patients who are growing their own cannabis; or obtaining it from compassionate suppliers or the illicit market.

Canada and many of the state programs in the United States allow patients and designated carers to grow their own cannabis. Patients can also access affordable cannabis from not for profit associations and small businesses.

In the US, the Obama Administration also made directives that the DEA and other agencies are not to use federal law enforcement measures against patients, carers, and suppliers in the States that have implemented medical programs as long as they have in place adequate health and safety standards administered by State Health and other departments.

The use of cannabis for medical purposes in Australia is not new. For decades, thousands of patients have turned to growing their own cannabis, as a means to obtain an affordable and safe supply of cannabis instead of having to deal with criminals.

The untaxed and unregulated black market has flourished even more because the Federal Government and state governments have failed to adopt sensible law reform policies. Many patients and carers are not only getting ripped off by criminals; they are also at risk of being arrested and charged and their medicines confiscated by police. They also have no guarantee that what they are buying is even fit for human consumption.

Patients who are “out of necessity” growing their own cannabis, or obtaining it from compassionate suppliers or from the black market should not continue to be criminalised under unjust state criminal laws, and be forced to choose between breaking an unjust law and suffering pain or death needlessly.

Despite royal commissions, inquiries, and calls from the public going back to the 1970’s, consecutive federal and state governments have failed to introduce legislation to regulate cannabis.

Instead the black market has been allowed to flourish while patients have had to live like criminals and be subjected to discrimination and alienation in health, housing, education, employment, travel and family and personal relationships.

Amnesties will not go far enough. When and if cannabis becomes legally available in Australia under the Federal Government’s legislation, it will be expensive.

Patients and carers need long-term sensible reform measures and for the states to introduce alternative legislation for the introduction of statewide medical cannabis programs with approvals that will exempt patients, carers and genuine compassionate suppliers from being charged with criminal offences under unjust state laws.

In the interests of all Australian patients we are calling on the Australian Parliament to support the Notice of Motion and to do whatever possible to rectify the other issues we have raised.

Please put the health, welfare and human rights of patients before profits and politics, whether the cannabis comes from within Australia from a federal or a state government agency, or from a commercial supplier, or whether it is imported in the interim, or whether the patient is growing their own cannabis plants or obtaining their cannabis medicines from a not for profit or genuine compassionate supplier.

> *Patients with life threatening conditions or chronic and disabling conditions should not have to wait 5 - 10 years for life saving and quality of life medicines to be made available, or drag themselves through unnecessary bureaucratic obstacles at the very time when they are most vulnerable and in need of support.*
>
> *No patient or their carer should have to choose between breaking an unjust law risking criminal charges and needless suffering, pain or death.*

Thank you for taking the time to read our submission.

NOTE: We have provided some more information on the TGA patient access pathways below. Please also visit the TGA and ODC websites, and Queensland Health and other state health agencies websites.

You can also find further information on the Special Access Scheme below, and can also read our other submissions on our website or visit our Facebook page.

Further Information: TGA Patient Access Schemes

Access to "Unapproved/Unregistered" Cannabis Medicines

Under the TGA patients have always been able to access, through their doctors, unregistered Schedule 9 cannabis, cannabinoids and cannabis resin under the SAS, and could also import these from overseas. Under the TGA patients have always been able to access and import other Schedule 9 substances such as heroin, and cocaine. Most states have had provisions for exemptions to access Schedule 9 substances, whereas Queensland had an outright prohibition on access to all Schedule 9 substances.

Narcotic Drugs Act 1967

Due to constitutional limitations under Australia's federated system of government, the Australian Government has full control over the import, export and cross-border trade of cannabis, and shared responsibility with the states on the cultivation, manufacture, and supply of cannabis, whereas dispensing, possession, and administration of cannabis are covered under state laws.

Provisions were also included for a separate licensing and permit scheme to regulate the manufacture of cannabis in accordance with the *Therapeutic Goods Act.* Patient access remains under the TGA pathways that provide for patient access to unapproved medicines in clinical trials, SAS and authorised prescribers.

Cannabis cultivated in Australia can only be used to conduct clinical trials and to develop therapeutic products for supply to patients in accordance with the *Therapeutic Goods Act.* Applicants for licences must have an identified and described line-of-sight to prescribers and patient groups in accordance with the *Therapeutic Goods Act,* as well as significant security requirements.

For the Federal Government's legislation to be fully implemented, the states and territories also need to amend their own laws or introduce new laws, as the states have shared control around cultivation, manufacture, supply and use of cannabis within their own jurisdictions under state health and criminal laws.

The ODC are responsible for granting licences and permits that authorise the cultivation and manufacture of cannabis and cannabis products under the *Narcotic Drugs Act.*

The import and export of cannabis, cannabis resin, and cannabinoids is regulated under the *Customs (Prohibited Imports) Regulations 1956*, and *Customs (Prohibited Exports) Regulations 1958.* The ODC also administer a regime for licit drugs covering border controls, manufacture and domestic transactions. The Commonwealth has not made any provisions to date to cover the export of locally made cannabis or cannabis products.

The *Therapeutic Goods Act* has always provided for a number of exemptions and special use provisions to allow patient access to potentially any unapproved or unregistered therapeutic product, including cannabis medicines that are not listed on the Australian Register of Therapeutic Goods (ARTG), or available in Australia.

Under the title of Patients Rights - *right of access*, the TGA guidelines state that individual patients can access unapproved therapeutic goods under a range of circumstances such as:

- early access for terminally ill patients to almost any product, including experimental and investigational products (see Category A);
- access to products which have been withdrawn from the Australian market for commercial or other reasons;
- access to products provided initially to patients through a clinical trial while a marketing application is being considered; and
- access to products available overseas but not marketed in Australia (Category B).

Patients have always been able to access potentially any unapproved cannabis medicine, including Schedule 9 cannabis and tetrahydrocannabinols (THC) under the special use and exemptions provisions in the *Therapeutic Goods Act 1989*. The TGA patient access pathways are:

- Special Access Scheme (SAS)
- Authorised Prescribers Scheme
- Clinical Trials
- Personal Importation

In addition, a doctor or pharmacist or a sponsor can apply to the ODC to import potentially any Schedule 4, 8 or 9 unapproved botanical or synthetic cannabis medicine into Australia from overseas under the *Customs Import Regulations.*

Special Access Scheme

Under the SAS any registered medical practitioner (General practitioner or specialist) can potentially supply any unapproved medicine to a patient but only on a case-by-case basis. Under the SAS there are no age restrictions, or restrictions on the types of medical conditions that can be treated with unapproved medicines.

Patient Categories

Under the SAS there are two categories of patients.

- Category A – TGA notification only
- Category B – TGA approval for all other patients

The choice of the classification of a patient under the SAS lies with the doctor, not with the TGA or the State. However the TGA and the states have put in place barriers that have changed the scope of the SAS for access to cannabis medicines, and that do not apply to any other medicine under the SAS, and that only serve to delay access and come between the doctor patient relationship.

Definition of Category A - Therapeutic Goods Regulation

> *"persons who are 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." All other patients can access unapproved medicines under Category B which needs TGA and State approval."*

This interpretation is very broad and would include many serious life threatening medical conditions as well as terminal conditions.

Interpretation of Category A - Australian Parliament 1991

The way the definition of Category A was intended to be interpreted can be gained by reference to the discussion in the Australian Parliament in 1991 at the time the definition was being framed for inclusion in the Act. Senator Tate made the following statement:

> *"when people are confronting the certainty of death and have a terminal or life-threatening illness, special provisions clearly ought to be made to help them psychologically face that prospect by giving them assurance that virtually whatever they wish, by way of* ***administration of a drug of which they have learnt****, can be undertaken" (Hansard, Senate 12 December 1991)."*

Category A - TGA Notification Only

If a medical practitioner forms the view that his or her patient fits the Category A definition (life threatening condition), the medical practitioner can supply potentially any unapproved therapeutic good to the patient without the approval of the TGA. The medical practitioner only needs to notify the TGA that they are supplying an unapproved medicine for treatment of a patient. The doctor completes the Category A form, and must send it to the TGA within 28 days.

The Category A form acts as the 'Authority to Supply' and provides the doctor with the legal authority to obtain or supply the unapproved product.

Prior to 1 November 2016 - Patient Access to Unapproved Therapeutic Goods

Prior to 1 November 2016, a registered medical practitioner who forms the view that his or her patient fitted the Category A definition, could supply any unapproved therapeutic good, except for substances listed in Schedule 9

without TGA approval. Regulation 12A - Unapproved medicines and biological - exemption in life threatening cases provided:

> (1) For the purposes of subsection 18(1) of the Act, all medicines, other than medicines of a class or kind listed in the 9th Schedule to the Poisons Standard, as in force from time to time, are exempt from the operation of Part 3-2 of the *Therapeutic Goods Act* …

Therefore prior to November 1 2016, patients could access cannabidiol (CBD) listed in Schedule 4, and nabiximols, dronabinol and nabilone listed in Schedule 8 under Category A. If a Category A patient needed access to cannabis or tetrahydrocannabinols (THC) they could only access them under Category B as they were still listed in Schedule 9.

Supply from Within Australia

If an unapproved medicine is available from within Australia, the Category A form can be sent direct to the sponsor or the pharmacy.

Importation

While patients can import cannabis medicines, it is almost impossible for most patients as it is difficult to obtain a supply from overseas, and there are even more bureaucratic processes with import and export licenses and permits.

If the cannabis products are not available in Australia, either the doctor or a pharmacist can apply to the ODC for an import licence, and a permit for each product. These documents are sent by post back to the doctor or pharmacist who is required to send originals by airmail to the overseas supplier for them to obtain the export approval.

Rescheduling of Cannabis and Tetrahydrocannabinols

In January 2016 the TGA commenced public consultation on the down-scheduling of cannabis and tetrahydrocannabinols (THC) from Schedule 9 to Schedule 8 in the Poisons Standard.

Effect of the Government's Amendments - Category A

On 1 November 2016, at the same time the Federal Government down-scheduled cannabis and tetrahydrocannabinols (THC) from Schedule 9 to Schedule 8, without any prior warning or public consultation, Sussan Ley also introduced the Federal Government's discretionary amendments to the *Therapeutic Goods Regulation* that will have the adverse affect of denying patients with life threatening conditions access to any cannabis medicines under Category A as follows:

Schedule 4: Cannabidiol (CBD) – No Access under Category A

Schedule 8: Cannabis (dried bud for vaporising), tetrahydrocannabinols (THC), nabiximols (botanical THC and CBD), nabilone (synthetic THC) and dronabinol (also synthetic THC) – No Access under Category A

Please note: Prior to the changes patients were permitted access to cannabidiol (CBD) listed in Schedule 4 and nabiximols, dronabinol and nabilone listed in Schedule 8 under Category A.

Instead of being afforded fast-tracked access to cannabidiol (CBD), cannabis, tetrahydrocannabinols (THC), nabiximols, nabilone and dronabinol under Category A, all patients who fit the Category A definition, will need to access all forms of cannabis medicines under Category B which can be a very costly, time consuming, convoluted and stressful process for doctors, patients and their carers.

Under the Federal Government's proposed amendments, the doctor will need to apply for mandatory TGA approval under Category B, even if the doctor has determined that his or her patient fits the Category A definition.

Category B - TGA and State Approval

Under the Category B process, doctors must obtain approval from the TGA, and then state approval under another convoluted process that duplicates the TGA process. Cases may also be referred to a state advisory panel. In Queensland it can take up to 90 days for Queensland Health to give the doctor a decision.

Dispensing - Community Pharmacy

In some states if the cannabis is dispensed from a community pharmacy, the pharmacist also need to prepare a cannabis dispensing management plan, and apply for state approval to obtain and dispense the cannabis. This process can take up to another 90 days.

Monitoring and Reporting

Doctors are also required to send regular reports on the progress of the treatment to both the TGA and state health departments. Patients are also required to undergo regular testing and obtain blood tests, EEG, and MRI reports and updated specialist's reports at the request of both the TGA and state health.

This adds more delays and more stress for patients and carers as it can take months waiting for tests and specialist appointments especially in the public system. Private specialists are very expensive, and do not always bulk bill. The costs for patients are unreasonable with both the TGA and state health departments requesting ongoing tests and updated specialist reports.

Repeat Supply

Doctors who have already obtained TGA and state approval to supply cannabis under Category B, still need to reapply through the TGA and state processes again, for each and every subsequent supply. If the cannabis is imported the pharmacist also needs to go through the import process again for each subsequent supply.

Other conditions

The states are also imposing unreasonable conditions for patients who access dried bud, such as the use of TGA approved vaporizer, or approved vaporizers from an overseas jurisdiction that is comparable to Australia.
There are currently no vaporizer devices on the ARTG or available for supply in Australia. Canada, and Israel are the only overseas jurisdictions that have health-approved vaporizers but do not permit exports.

Patients are required to purchase the vaporizers from the company direct, and import them into Australia under the Personal Importation Scheme. In 2016 the company in Germany exporting the vaporizers advised, that a US company is seeking registration of its vaporizer devices in Australia in 2017.

Importing - SAS

As there is still no legal supply of cannabis available in Australia, some patients who need urgent access are trying to import their cannabis as an interim measure. If the cannabis is imported, there are further delays as the doctor or a pharmacist also needs to obtain an import licence and permit for each product from the ODC.

Depending on the overseas country, there can be significant delays with the supplier applying for an export license and permits. Even if the overseas supplier holds an export licence, there can be significant delays waiting for export permits and further delays with manufacturing and shipping times.

More about the Medical Cannabis Advisory Group QLD

The Medical Cannabis Advisory Group Queensland has been advocating for the lawful use of cannabis for medical purposes. Some of the activities we have undertaken over the past 2 years include:

- Submissions for an amnesty and statewide medical cannabis program
- Submissions and evidence in the Queensland Parliament inquiry into the Medicinal Cannabis Bill (QLD) 2016
- 4 petitions tabled in Queensland Parliament sponsored by the Clerk of Parliament
- 3 change.org petitions
- Corresponding and meeting with Commonwealth and State Parliamentarians and their advisors, government agencies, health and legal professionals and other stakeholders.
- Development of a Sample Cannabis Treatment Plan and Informed Consent Form
- Media interviews and public speaking
- Protests and rallies
- Film night screening of 'A Life of its Own'
- Website, and Facebook page

You can also find further information about our campaigns, and submissions on our website and our Facebook page.