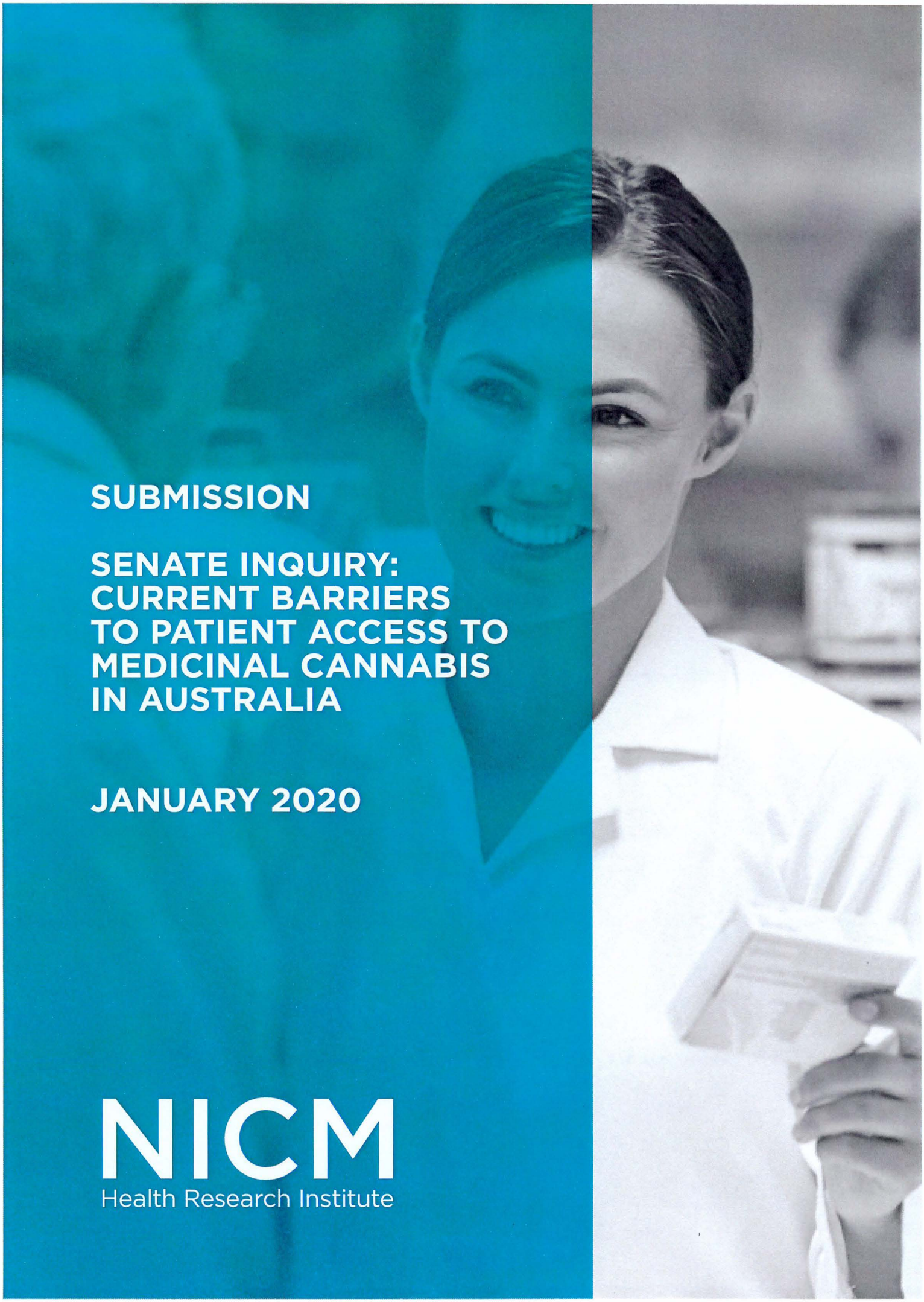

SUBMISSION

SENATE INQUIRY: CURRENT BARRIERS TO PATIENT ACCESS TO MEDICINAL CANNABIS IN AUSTRALIA

JANUARY 2020

NICM
Health Research Institute

INTRODUCTION

Western Sydney University's NICM Health Research Institute (NICM HRI) is Australia's leader in integrative and complementary medicine research and policy. Established in 2007 by the Commonwealth Government and NSW Government, the Institute provides leadership and support for strategically directed research into integrative medicine, to promote the translation of evidence into clinical practice and develop relevant policy to benefit the health of all Australians. As an Excellence in Research for Australia (ERA) 5* rated institute, NICM HRI is globally recognised for its world-class research and innovations in complementary medicine. The Institute is Australia's most awarded ERA 5 institute in the field of complementary medicine research, rated for three consecutive triennium, 2012, 2015 and 2018. NICM HRI's research includes clinical trials, laboratory testing and policy work, with research efforts concentrated in cardiovascular and metabolic disorders, neurocognitive and mental health disorders, women's sexual and reproductive health, cancer care, as well as emerging research areas such as medicinal cannabis.

NICM HRI's state-of-the-art laboratories are certified with the Australian Therapeutic Goods Administration (TGA) and were recently awarded a medicinal cannabis manufacture licence from the Office of Drug Control (ODC). The Institute is also home to the Australian Medicinal Cannabis Research and Education Collaboration (AMCREC), an initiative that brings together leading expertise across multiple scientific disciplines, including plant genetics, phytochemical analysis and pharmacology, and provides a platform for high quality, independent research and education. NICM HRI was part of a collaborative team that delivered the first RACGP Category 1 Medicinal Cannabis education program for medical practitioners in Australia, which has been identified as an important aspect to improving patient access across the country.

In 2018, NICM HRI also held an inaugural international medicinal cannabis research symposium, attracting leading cannabis researchers and experts across the globe. The second symposium is planned for October 2020 at Westmead.

On 14 November 2019, the Senate referred an inquiry into the current barriers to patient access to medicinal cannabis in Australia to the Senate Community Affairs References Committee for inquiry and report by 26 February 2020. Submissions are requested by 17 January 2020.

This submission outlines the response of NICM HRI to the Terms of Reference listed for this Senate Inquiry.

NICM HRI's position can be summarised as follows:

- If sufficient evidence exists that links compositional definition with safety, clinical effectiveness and cost effectiveness, then the Pharmaceutical Benefits Scheme (PBS) should be available and assist patient access to medicinal cannabis.
- Cannabis is a complex matrix of multiple phytochemical active constituents, and provision within the PBS would need to accommodate this complexity.
- Australia appears to have one of the more restrictive regulatory models in comparison to those established in other parts of the world. This includes both patient access and the licencing requirements for cultivators, manufacturers and researchers of legal medicinal cannabis.
- The high cost of legal medicinal cannabis products in Australia should be considered a significant barrier to access, causing legitimate patients to seek illicit cannabis for therapeutic use.
- Current drug driving laws as they relate to cannabis across Australia should be considered a significant barrier to legitimate patient access in their current format and are in need of review.

*ERA is a national evaluation of research quality in Australian universities conducted by the Australian Government. It is administered by the Australian Research Council (ARC). ERA5 is the highest rating, characterised by evidence of outstanding performance well above world standard presented by the suite of indicators used for evaluation.

TERMS OF REFERENCE

a. the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials

The appropriateness of any medicinal cannabis regulatory model should be evaluated based on the ease of use by clinicians, and the speed of access to a safe, quality-assured product provided to the end user at an affordable price. Adequate resources and content expertise at the federal and state/territory government levels are essential to ensure this is achievable.

b. the suitability of the Pharmaceutical Benefits Scheme (PBS) for subsidising patient access to medicinal cannabis products

If sufficient evidence exists that links compositional definition with safety, clinical effectiveness and cost-effectiveness then the PBS should be available and assist patient access to medicinal cannabis. Cannabis is a complex matrix of multiple phytochemical active constituents and provision will also need to be made within the PBS to accommodate this complexity.

To date the majority of medicinal cannabis products being prescribed in Australia are accessed primarily through the SAS Category B pathway, which is intended for exceptional clinical circumstances and contains products predominantly classified as unapproved medicines. The majority of the medicinal cannabis products currently accessible to Australian patients are imported and expensive, due chiefly to the nascence of the current Australian medicinal cannabis industry to be cost-competitive. To date only two Australian companies have brought a product to market since the amendments to the *Narcotic Drugs Amendment Bill 2016*, despite numerous companies having been issued ODC licensure since this time.

If patients are not able to access affordable, quality-assured medicinal cannabis products that can be prescribed and monitored by their medical professional, then they will likely resort to the illicit market. As an example, recent research published by NICM HRI has demonstrated that women with endometriosis are using illicit cannabis to manage their pain and associated symptoms.[1,2] Unpublished research from focus groups with women with endometriosis has also identified that cost is a major limiting factor, potentially driving many to use illicit products over legal ones. Access to unregulated illicit markets to obtain medicinal cannabis raises obvious public health concerns due to potential exposure to adulterated and non-quality assured product of unknown provenance, removing patients from medical supervision and closing channels of effective communication regarding possible risks and side effects.

c. the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes

The Commonwealth has worked with state and territory governments to streamline and improve the speed of medicinal cannabis access since first inception. The TGA has consistently fast approval times, usually within 48 hours, according to our researchers' ongoing discussions with practising medical cannabis prescribers across NSW and Victoria. Where inconsistency seems to occur is:

(1) the speed with which the various states and territories approve access after federal approval,

(2) if specialist medical support is required with medicinal cannabis applications, and

(3) the amount of approvals that have been granted across the states and territories.

There exists a lack of regulatory harmonisation and consistency across the states and territories currently in Australia. This may be contributing to the phenomenon witnessed in the early years of medicinal cannabis implementation in the USA[3,4] of "cannabis refugees", whereby patients and/or their families temporarily relocate to regions that are more accommodating to medicinal cannabis access, whether in Australia or abroad. A harmonised and consistent access pathway involving all key stakeholders should be

1 Armour M, Sinclair J, Chalmers KJ, Smith CA. Self-management strategies amongst Australian women with endometriosis: a national online survey. BMC Complement Altern Med. 2019 Jan 15;19(1):17.
2 Sinclair J, Smith CA, Abbott J, Chalmers KJ, Pate DW, Armour M. Cannabis Use, a Self-Management Strategy Among Australian Women With Endometriosis:Results From a National Online Survey. J Obstet Gynaecol Can. 2019 Nov 7.
3 Phillips D. Marijuana refugees: Families relocating to Colorado so kids can use cannabis oil to fight seizures, legal landscape changing in other states. Missoulian. 2014. p. https://missoulian.com/lifestyles/health-med-fit/marijuana-refugees-families-relocating-to-colorado-so-kids-can-use/article_0e0670aa-dabb-11e3-8c2d-019bb2963f4.html.
4 Marijuana Refugees: Looking for new homes in pot-legal states. NBC News; 2014. p. https://www.nbcnews.com/business/consumer/marijuana-refugees-looking-new-homes-pot-legal-states-n22781.

prioritised to increase the likelihood of patients seeking legitimate access.

d. Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access

Australia appears to have one of the more restrictive regulatory models in comparison to those established in other parts of the world such as Canada, Israel, the Netherlands and certain states within the USA. This includes both patient access and the licencing required for companies to cultivate, research and manufacture medicinal cannabis products. Excessively onerous restrictions on patient access may inadvertently encourage prospective patients to use illicit market products.

e. the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients

There is a large amount of text (online and printed) on how medical practitioners can utilise the SAS Category B and Authorised Prescriber Schemes for medicinal cannabis applications on the TGA website, including various state and territory contact details. This takes an extensive amount of time to read through and may not suit the time poor nature of busy medical clinicians, with many simply too busy to engage in the process and/or referring patients to speciality cannabis clinics. Short courses on medicinal cannabis prescribing can train clinicians on the various approval processes, but these are inconsistently available and have limited places on offer. These training programs could be further supported. An online portal utilising videos and infographics to outline the prescribing process may be a useful tool to increase the education of doctors in this emerging field.

f. the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications

In October 2019 a medicinal cannabis education event with over 130 medical practitioners and nurses in attendance was hosted at Prince Charles Hospital in Brisbane. Notably, none of the attendees had studied the ECS in their undergraduate or postgraduate training programs.

NICM HRI was part of a collaboration which delivered the first category 1 Royal Australian College of General Practitioners (RACGP) accredited medicinal cannabis education course in Australia. The curriculum included an overview of the anatomy, physiology and dysfunction of the ECS.

The TGA has developed guidance documents on the use of medicinal cannabis in conditions such as paediatric epilepsy, multiple sclerosis, nausea and vomiting, palliative care and chronic non-cancer pain, but other conditions including post-traumatic stress disorder (PTSD), fibromyalgia, anxiety, ulcerative colitis, autism and insomnia[5] are also being prescribed and approved, which is encouraging.

g. sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened

There is a relative paucity of balanced, good quality and independent information available to medical practitioners currently on the clinical uses and prescribing of medicinal cannabis in Australia. Medicinal cannabis companies commonly provide such information to doctors, however, this is not necessarily independently assessed. Recommendations on improving this area could include the TGA publishing guidance documents of a clinically useful nature on some of the emerging conditions being prescribed for by Australian doctors, such as fibromyalgia, anxiety and PTSD. Further, the preparation of generalised guidance documents of an educational nature specific to medicinal cannabis prescribing and the ECS, such as is observed in the Green Book of the Israeli Ministry of Health, would be an excellent resource for Australian medical doctors

h. delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products

As addressed above.

i. the current status of the domestic regulated medicinal cannabis industry

As addressed above.

5 Request for documents relating to Special Access Scheme Category B pathway for medicinal cannabis products for the period 1/11/2016 to 31/08/2019 - FOI 1311. Therapeutic Goods Administration; 2019.

TERMS OF REFERENCE CONTINUED

j. the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime

The challenges that patients may face attempting to access legal medicinal cannabis under Australia's current regulatory regime include:

(1) finding a medical prescriber willing and experienced to assist,
(2) the time it takes to actually receive approved medicine,
(3) ensuring a continuing ongoing and unchanging supply of product,
(4) being able to afford the ongoing costs of the medicine, along with
(5) possible social, religious or cultural discrimination due to the stigma associated with consuming cannabis.

All of these factors can potentially negatively impact the physical and mental wellbeing of patients, and compound patient suffering.

k. the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally

Problems described above are exacerbated in remote and rural areas due to shortage of trained clinicians.

l. the significant financial barriers to accessing medicinal cannabis treatment

Based on feedback from current legal patients of medicinal cannabis for chronic pain conditions, monthly expenditure can range from between $250 to $400 per month, with an average cost of $353 per month.[6] For comparative purposes, 53% of women using illicit cannabis to manage the pain and symptoms of endometriosis reported spending less than $100 per month[2] however, other Australian surveys of people using illicit cannabis for therapeutic purposes suggest mean monthly expenditures of between $274 - $378.[7] The cost of using legal products is considerably higher for some specific conditions such as paediatric epilepsy, with costs estimated to be approximately $992 per month on average.[6] Medical cannabis patients are at risk of taking less than the prescribed amount (i.e. underdosing) to make the medicine last longer due to the high cost and lack of government subsidy and anecdotal reports confirm this.

Medicinal cannabis products are dispensed by pharmacists in Australia, which is also contributing to high costs to patients. A 2018 report by Cannabis Access Clinics purports that pharmacy mark-up of medicinal cannabis products ranges between the average of 26% to up to 140%.[6] According to advocates, the cost structures implemented by some medicinal cannabis specific clinics may also contribute to the cost burden to patients.[8] Chronically ill patients, particularly if on pensions or disability support, may find the financial burden of legal medicinal cannabis too great, risking a diversion to illicit market products.

m. the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that

Estimates of how many Australian patients that are currently utilising unregulated illicit supply of cannabis for therapeutic purposes varies, but ranges between 100,000 to 200,000 people.[9] Cannabis is the most widely used illicit drug in Australia,[10] with data suggesting Australia and New Zealand are some of the largest consumers of illicit cannabis in the world per capita with significant proportions likely to be using cannabis for therapeutic benefit and not solely recreational use.[11]

Drivers that may be contributing to the demand of illicitly supplied products include:

1. The high cost of legal medicinal cannabis products currently in Australia;
2. Finding medical practitioners appropriately educated in the ECS and medicinal cannabis prescribing;
3. Finding medical practitioners willing to prescribe medicinal cannabis and go through

6 Australian Medicinal Cannabis Pricing Analysis. Cannabis Access Clinics; 2018; Available from: https://cannabisaccessclinics.com.au/wp-content/uploads/2019/06/CAC_MedicinalCannabisPricingAnalysis_Online.pdf.
7 Lintzeris N, Driels J, Elias N, Arnold JC, McGregor IS, Allsop DJ. Medicinal cannabis in Australia, 2016: the Cannabis as Medicine Survey (CAMS-16). Med J Aust. 2018 Aug 3;209(5):211-6.

8 Kerr J. Cannabis users say clinic is 'cash grab'. Courier Mail. 5/10/2018.
9 McGregor I. Why so few Australians are using medicinal cannabis on prescription. Sydney Morning Herald. 2017.
10 Alcohol, tobacco and other drugs in Australia. Australian institute of Health and Welfare: Australian Government; 2019; Available from: https://www.aihw.gov.au/reports/phe/221/alcohol-tobacco-other-drugs-australia/contents/drug-types/cannabis.
11 Global Overview of Drug Demand and Supply. United Nations Office on Drugs and Crime; 2019; Available from: https://wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_2_DRUG_DEMAND.pdf.

appropriate access pathways;

4. Patients not having a medical condition deemed suitable for consideration by federal or state/territory regulatory agencies, or being rejected by the regulator or medicinal practitioner based on their presenting condition and symptomatology;
5. Patients who have been using illicit supply (via illicit purchase or home cultivation) and getting good therapeutic results, but when switching to legal supply experienced suboptimal results, perhaps due to differences in cannabinoid ratios or cannabinoid/terpene profiles;
6. Patients who feel judged or embarrassed to discuss the use of medicinal cannabis with their medical practitioner due to associated stigma, and therefore use illicit cannabis to self-manage and do not inform medical professionals;
7. Patients who are concerned, through potential privacy breaches, that it could become known that they utilise medicinal cannabis and the risk this could pose to employment opportunities or their standing in their individual communities;
8. Patients who were using cannabis illicitly for therapeutic purposes before legislation was enacted and continue to source their own supply illicitly specifically of cannabis flower (i.e. flos, bud) for smoking or vapourising. Smoking and vapourising are the most common dosage forms utilised by those using illicit cannabis for therapeutic purposes, which has been demonstrated in recent surveys.[2,7] Many patients find this dosage form has faster onset of action than orally manufactured medicinal cannabis products, and is easier to titrate their required dose. Based on prescription numbers and dosage forms used through the SAS Category B pathway, cannabis flower appears to be prescribed very rarely in Australia, due largely to the perceived risk of harm of smoking or vapourising held by prescribing medical practitioners.

n. any related matters.

The current drug driving laws in Australia should be considered as a significant barrier to patient access in their current form. Saliva swab tests utilised by police forces across Australia's states and territories are designed to detect the presence of the cannabinoid tetrahydrocannabinol (THC), but do not calculate or assess the level of physical or cognitive impairment that the recipient of the test is currently experiencing. Automatic loss of licence, fines or potential gaol time (if having previous convictions) could be the consequence of testing positive, even though the person involved may be a legitimate medical cannabis patient under the care of a doctor.

Unpublished qualitative data from focus groups on women with endometriosis conducted at NICM HRI demonstrated that driving is a key factor to not using legal medicinal cannabis as they do not wish to break drug driving laws and risk a criminal conviction. Due to current drug driving laws, recruitment of patients for medicinal cannabis trials can be difficult as inclusion criteria stipulates that participants cannot drive during the trial to comply with current laws. Due to the fact that cannabinoids can stay in the body for an extended time due to their lipophilic nature, it is clearly demonstrable that a person could test positive for THC presence, despite not being intoxicated or physically or cognitively impaired, under the current laws.

As part of this review specific to barriers to patient access, the Federal Government should prioritise reviewing these laws for what is now a legitimate prescribed medicine in Australia. Opioids and benzodiazepines are commonly prescribed by Australian medical doctors (with less regulatory burden), and produce significant side effects such as physical and cognitive impairment, yet are not tested for in current drug driving tests, with patients essentially being told by their medical practitioner to not drive if they feel intoxicated.

nicm.edu.au

Contact:
Professor Alan Bensoussan
Justin Sinclair

p. +61 2 9685 4700
e. nicm@westernsydney.edu.au
a. Locked Bag 1797 Penrith NSW 2751 Australia

WESTERN SYDNEY
UNIVERSITY