Senate Standing Committees on Community Affairs Inquiry
Current barriers to patient access to medicinal cannabis in Australia

Submission to the Inquiry

About Us
Currently the Medical Cannabis Knowledge Network comprises a small, informal group of cannabis industry professionals, patients/carers, healthcare providers and others from Australia and overseas with a strong interest in how the use of cannabis products for medical purposes is developing and will likely further develop locally and elsewhere in coming years.

Our purpose is share knowledge & information both online and in the real world and to encourage respectful discussion between members based on informed opinion from a variety of perspectives and disciplines. Such cognitive diversity, is we believe, key to any rational exploration of this topic and as such we commend the below Submission to the Inquiry.

Background to the Inquiry
The 2016 Amendments to the Narcotic Drugs Act 1967 and concomitant rescheduling of cannabis allowing its cultivation and use for medical purposes represented an historic moment in Australia's position in respect of the drug itself and in terms of drug reform generally.

Coming after a wave of public and media pressure, detractors then and more recently, have criticised the move as being ill-considered and pandering to clinically and scientifically unsound popular sentiment[1]. Indeed, the Government's own Regulation Impact Assessment in respect of the 2016 legislation hints strongly that it (the legislation) was being introduced, at least in part, as a response to proposed State legislation in Victoria which would have proceeded without Commonwealth sanction[2]. Such a development, it was believed, may well have placed Australia breach of its obligations under international drug treaties while the 'go it alone' stance of the newly elected Victorian Government was itself largely as a result of strongly expressed public opinion.

The Narcotic Drugs Act Amendments and rescheduling of cannabis therefore served to keep Australia compliant with relevant treaties *and* to create a national framework in which the drug's regulation could be handled at Commonwealth level under the auspices of the Therapeutic Goods Act 1989 while interacting with laws and regulation at State and Territory level.

This solution, it should be noted, also offered an alternative to another Federal Bill active at the time – the cross-party 'Regulator of Medicinal Cannabis Bill' which had been passed by the Senate in October 2014.

That Bill had proposed that a new, stand-alone, single-purpose body be created to regulate cannabis specifically, outside of the Therapeutic Goods Act and therefore the jurisdiction of Government's existing medical regulator the Therapeutic Goods Administration (TGA). This option was rejected however, largely because it was strongly opposed by what might be termed Australia's 'medical establishment', which insisted cannabis had to be viewed and treated 'like all other (conventional) medicines' and regulated as such through the existing system[3].

Access Pathways
Without setting out in un-necessary detail how medicines are regulated and approved for use in Australia, it is however important to note the following:

1. In 2016 the Australian Parliament decided that cannabis products should be made available only through a doctors' prescription and that
2. Cannabis products should be regulated under the Therapeutic Goods Act thus by the TGA;
3. Just one cannabis-based medicine (nabiximols tradename Sativex®) has thus far been approved for use in Australia;
4. All other cannabis products are therefore 'unapproved' for use in this country and are only accessible through pathways that allow for unapproved medicines to be made available on prescription, these being the Special Access Scheme Category B requiring TGA approval of those prescriptions; prescription by an 'Authorised Prescriber', and clinical trials.
5. In respect of Point One, unless Parliament can be persuaded that a formal doctor's prescription should *not* be the avenue through which cannabis products are made available to patients (for example Canada and many US States use less formal 'approval notes' enabling dispensary or online purchases), then regardless of what arrangement is employed to facilitate access administratively speaking, the decision-making of doctors remains the sole route by which such products may legally be obtained.

Currently
Since 2016 prescriptions and approvals for cannabis products via the above-mentioned pathways have risen steadily though unevenly across States and Territories, likely as a result of the establishment of specialist 'cannabis clinics' to service an evident need.

According to market consultants Freshleaf Analytics, there are currently around 10,000 'active' users of prescribed medicinal cannabis products in Australia, and the organisation expects to see this number rise throughout the next year. *'(We) see patient numbers grow on average 15-20% month-on-month,'* it says. *'By the end of 2020, while growth rates will slow we predict that the market size will have expanded to 30-50,000 active patients, representing annualised product sales in excess of AUD $100M.*[4]'

Patient Numbers – Regulated and Unregulated Markets

Nonetheless, these 'legal' patients must be seen in relation to the considerably larger number of individuals that continue to rely on unregulated ('black') market products. The latter have previously been estimated at around 100,000 [5] but in reality, this volume is probably much higher. For example, a recent poll[6] of a large (n = >10,000) representative sample of the UK population discovered 2.8% (1.4m) of British citizens use illicit cannabis products to treat diagnosed chronic health conditions. Since there is little to suggest our own population would behave any differently, extrapolating such a figure would indicate around 689,000 sick Australians are doing likewise, representing a significant public health and societal risk.

Recent Review Exercise

In October 2018, a Statutory Review into the operation and implementation of the Narcotic Drugs Act Amendments was initiated with a Final Report[7] published in September 2019. With reservations and 26 formal Recommendations, the Review concluded that Australia's Medicinal Cannabis Scheme had been '*resoundingly successful'* though did acknowledge, along with other key findings, that, even if outside its terms of reference, where patient access to the drug was concerned (the subject of this current Inquiry) some saw the Scheme as having '*failed to fulfil expectations'*.

This conclusion was perhaps unsurprising since cannabis advocacy groups had long argued – and successfully constructed and established a media narrative[8] – that the Scheme had indeed been failing patients due either to excessive red tape in securing prescriptions and approvals for such products, or the expense involved obtaining them where approvals had been forthcoming, or both.

Differing Positions

That narrative however stands in stark contrast to the views of 'establishment' bodies such as Royal Medical Colleges, the Australian Medical Association, conservative public health experts and indeed the Cth Department of Health via the TGA[9][10][11][12].

These individuals and organisations, as they consistently have for some years, maintain that a poor to non-existent evidence base exists as to the safety and efficacy of cannabis and cannabis products and furthermore that such unapproved products remain inappropriate for wide usage since they do not meet the conventional regulatory standards imposed on all other medicines in Australia. Therefore, they argue, such products might well be unsafe or unsuitable to prescribe and/or lack evidence as to their usefulness.

These conflicting positions – advocates on the one hand and sceptics of the drug on the other – had been conspicuous since around 2014 when public pressure to 'legalise medicinal cannabis' began building in earnest across much of Australia.

Understanding the Problem

In her 2019 paper '*The Challenge of Medicinal Cannabis to the Political Legitimacy of Therapeutic Goods Regulation in Australia*' Melbourne University Law School Fellow Penny Gleeson provides some excellent conceptual apparatus and a framework for understanding the tensions between these two positions, further refining the 'pro' and 'con' factions by discerning '*three voices of medicinal cannabis regulatory reform*'. The 'voices' Gleeson identifies comprise what she terms 'Dominant', 'Moderate' and 'Radical'.

'Each of these voices,' Gleeson contends, '*expressed a different conception about what constitutes 'medicinal cannabis', and indeed what cannabis is itself.'*[13]

> *'The 'dominant' voice asserted the position of the regulatory status quo to exercise a high degree of social and legal control over cannabis as an illicit substance. A more 'moderate', middle ground voice sought to embrace cannabis as both a therapeutic substance and a mechanism of delivering compassion to patients. A third, 'radical' voice conceived of cannabis as a mainstream substance for consumption that should be normalised and legalised. These perspectives in turn emphasised different epistemological traditions to justify their respective concepts of medicinal cannabis.'*[14]

This spectrum of 'epistemological traditions' and the marked antipathy between each of them is well evidenced across social and traditional media[15][16] and in Submissions to the numerous Public Inquiries (doubtless including this one) held at State and Federal levels[17][18][19][20][21][22] into possible solutions to the issue of medicinal cannabis use and availability in Australia. While Gleeson's 'Moderate and 'Radical' distinction insightfully explains why the cannabis advocacy movement in Australia is so fractious and disorderly, a key to understanding the antagonism by 'Moderates' and 'Radicals' alike toward the 'Dominant Voice' lies in question of what constitutes 'evidence'.

Considering the Evidence Base

For the 'Dominant Voice', whose practice is based on an Evidence Based Medicine (EBM) paradigm, 'evidence' in effect means data about a specific, standardised molecule (or variety of them) collected from various (usually three) phases of Randomised Controlled Trials for a particular indication – the conventional method of approving medicines for use in this country. Put another way, the individuals and organisations representing this position, believe, as pointed out by Caldicott *et al* (2018) '*that if cannabis is to be considered as a medicine, it must be considered as a 'new drug' rather than as a plant*' and this via '*pharmaceutical company processing of 'medicinal cannabis' to a narrow, single-agent spectrum of action*.'[23]

Medicinal Cannabis and Evidence Based Medicine

This should not be surprising, since EBM requires, according to Sackett *et al* (2000) *'a systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values*[24]. Wikipedia too (in this instance) puts it well, describing EMB as:

> *'….an approach to medical practice intended to optimize decision-making by emphasizing the use of evidence from well-designed and well-conducted research. Although all medicine based on science has some degree of empirical support, EBM goes further, classifying evidence by its epistemologic strength and requiring that only the strongest types (coming from meta-analyses, systematic reviews, and randomized controlled trials) can yield strong recommendations; weaker types (such as from case-control studies) can yield only weak recommendations…. (The term) has subsequently spread to describe an approach to decision-making that is used at virtually every level of health care as well as other fields (evidence-based practice).*
>
> *Whether applied to medical education, decisions about individuals, guidelines and policies applied to populations, or administration of health services in general, evidence-based medicine advocates that to the greatest extent possible, decisions and policies should be based on evidence, not just the beliefs of practitioners, experts, or administrators.'*[25]

Due to eight or more decades of complete prohibition there is, not unexpectedly, a relative paucity of such evidence for its safety and efficacy, and indeed a shortage of conventionally approved products themselves. Thus, for organisations such as the TGA, AMA and the Royal Medical Colleges, use of 'medicinal cannabis' *per se* is scientifically and clinically untenable

Alternative Views

Both the 'Moderate' and 'Radical' voices insist on the other hand that vast anecdotal evidence, based on the lived experience of countless thousands of individuals worldwide as well as within Australia, is ample demonstration that the plant itself represents a safe and highly effective medicine. This 'anecdotal evidence' they say, should be considered as valid 'demographic' (or 'real world') data and taken into account when regulating or prescribing such products, especially if added to the rapidly growing canon of laboratory and ethnographic research[26][27] together with the expansion of clinical practice and expertise with cannabis medicines evinced overseas[28].

Politics

While not shared by the Government or medical establishment (though long the position of the Australian Greens[29]), such a view did however win the support of Australian Labor in the run-up to the last General Election when the Party made a statement in which it made clear its position that:

> *'Unlike the Liberals, Labor understands that there is evidence to support the use of medicinal cannabis for a range of conditions, and believes that the federal government should play a national leadership role in expanding access.'*[30]

And, should it win, that it would:

> *'Build even more evidence for medicinal cannabis, including through facilitating Australian research, a potential Commonwealth trial, and consideration of overseas experience.'*[31]

Patient Safety

This is congruent with those of a 'Moderate Voice' (who wish to see high quality and regulated cannabis used under medical supervision) and arguments such as the below, which contend:

> *' ...denying patients legal access due to lack of the highest levels of scientific evidence means many are left with the only option of tackling complex health problems alone and without appropriate clinical oversight by a licensed medical practitioner.*
>
> *Such policy seems to contradict itself and is risking the health and safety of patients by subjecting them to illicit, unregulated products.'*[32]

They therefore ask:

> *'Is it not conceivably safer and within the scope of duty of care to medically monitor patient use of a regulated medicinal cannabis product for a condition with sub-optimal scientific evidence than to subject that patient by default to unregulated product and unsupervised care via illicit use?'*[33]

And they further point out that:

> *'According to the National Health and Medical Research Council (NHMRC), evidence comes in the form of systematic reviews (Level I), randomised controlled trials (Level II), pseudo-randomised controlled trials (Level III-1), comparative studies with concurrent controls (Level III-2), comparative studies without concurrent controls (Level III-3) and case series with either post-test or pre-test/post-test outcome measures (Level IV). This 'hierarchy of evidence' underpins the clinical decision-making process of government departments, research institutes*

and universities as well as individual medical practitioners making informed clinical judgements for the health and wellbeing of their patients on a day-to-day basis.

Of particular relevance to this discussion is the N of 1 clinical trial, which fits within the hierarchy of evidence framework. This level of evidence considers an individual patient as the sole unit of observation in a study investigating efficacy or side-effect profiles of different interventions, with the goal being to determine the optimal intervention for an individual patient using objective data driven criteria and outcome measures.'[34]

As a solution they suggest:

'Results of such (N of 1) studies can be collected and collated to ascertain proof of concept and establish a scientific rationale for treatment of a particular condition, which can then lead to more rigorous forms of evidence such as randomised, double blind, placebo controlled clinical trials being implemented.'[35]

'Establishment' Concerns

Although such an argument would seem reasonable, concerns by many healthcare professionals about therapeutic goods marketed and used outside of the usual frame of reference (the EMB paradigm) are understandable and undoubtedly genuine, as is their disapproval of what are seen as extravagant and unfounded claims by the still developing (legal) cannabis industry.

Speaking of the Canadian experience in a country where medicinal cannabis has been available since 2001, *Kahan et al* point out in the December 2019 edition of Canadian Family Physician:

'Health Canada is responsible for ensuring that pharmaceutical products are safe and effective. It approves products for sale after rigorous review of their safety and effectiveness, and it requires companies to develop a product monograph containing the indications, contraindications, and dosing for the product. Companies are not allowed to promote "off-label" uses of their product (i.e. for nonindicated conditions). Physicians are expected to be consistent with the product monograph in their prescribing of the product and in their educational presentations on the product. However, Health Canada does not require cannabis companies to produce and abide by a product monograph, listing the indications, contraindications, and dosing of their products. As a result, the educational programs the industry sponsors have no restrictions on their claims about their product. Furthermore, Health Canada has allowed the companies to produce cannabis with THC concentrations of 20% or more. Industry involvement in medical cannabis marketing and education has a very dangerous precedent: Purdue's marketing of OxyContin.'[36]

The above will likely appear disingenuous and callous to advocates and many patients just as *their* views seem unscientific and clinically unacceptable to practitioners of Evidence Based Medicine.

Public & Media Support

As had been the case in Canada however, crucial to the debate here in Australia is that public and media opinion clearly favours – as it has throughout the debate – those arguing for a more relaxed, inclusive and compassionate approach to the use and regulation of medicinal cannabis products as well as what constitutes an acceptable evidence base to justify its use in a clinical setting.

This support can be attributed in large part to the success of Australian advocates to win the hearts and minds of the public with stories of how the drug has transformed lives while forcing desperate parents, patients and their carers into the hands of the criminal underworld and law enforcement.

These, coupled with the fact that people are not blind to developments in other jurisdictions where, increasingly, cannabis is being made more widely available for medical or even recreational use, have resulted in up to 97% of the population[37] feeling it (cannabis) should be made more easily available for medical purposes.

Government Position
Meanwhile, the gulf between the respective positions of the 'dominant' and opposing voices within the debate has, we suggest, resulted in an uneasy compromise by Australian Governments in their approach to the drug's regulation. They have at once permitted patient access albeit on a limited basis while maintaining, as far as possible, the perspective and views of the medical establishment – in other words those of the 'dominant' – or 'prevailing' – voice.

Challenge to Regulatory/Medical Legitimacy
Given the 'win' in the court of public opinion by those of a 'pro cannabis' disposition however, and continued discussion of the matter, Gleeson asserts the situation has amounted, overall, to nothing less than '*a challenge to the legitimacy of the regulation of therapeutic goods in Australia,*'[38] and (we feel) by extension, that of the wider medical profession.

Citing social scientist David Beetham, Gleeson suggests at least one and (in our view) more likely two of the *'three 'dimensions' or 'elements' that are necessary for power to be considered legitimate'*[39] have been absent in respect of the TGA's position on the drug (and we would argue also the 'medical establishment') throughout the ongoing debate. Where these three elements (of 'legality', 'normative justifiability' and a 'shared moral order') are concerned, absence of the last of them often results, Gleeson writes, in '*public acts of protest, disobedience, and withdrawal of endorsement or recognition*'[40], all of which have been witnessed in relation to medicinal cannabis and the TGA, none of them, we suggest, civically beneficial. *Indeed, within in a public health context they are highly undesirable and even potentially dangerous.*

So, with what is inarguably a troublesome state of affairs, where do we take things from here?

Problem of Conventionally Regulated Products
The question itself is not easy, since, due to the protracted, expensive and (for cannabis) problematic process of product trialling and acquiring inclusion within the Australian Register of Therapeutic Goods (which catalogues medicines approved for use in this country) it is unlikely many further cannabis products will be registered or approved any time soon[41].

No Marketing of 'Cannabis' or 'Cannabis Products'
In keeping with its 'establishment' position meanwhile, the TGA recently indicated an apparent decision to 'clamp down' on what it sees as the 'marketing' of cannabis products and cannabis-related services and information provision which may compound and complicate matters still further.

Publication in October/November 2019 of its document '*Advertising guidance for businesses involved with medicinal cannabis products - Complying with therapeutic goods advertising requirements*'[42] reiterated what was already well recognised by those with an understanding of Australian therapeutic goods regulation – that *'advertising medicinal cannabis to the public is prohibited*' (p. 5) and that in promoting health services or businesses involved with medicinal cannabis, those businesses must not refer (p. 9):

> *'either overtly or by implication, to medicinal cannabis. This includes making references through:*
> • *company, business or trading names*

> • *product names or trade names*
> • *abbreviation or acronyms for the good*
> • *colloquial names*
> • *any other reference, including images, that are likely to draw the consumer's mind to medicinal cannabis.*

But in fact, the strictures described within the document appear to be more extensive than many (including ourselves) had previously imagined, since it also suggests even advocacy websites need to provide *'factual and balanced information about medicinal cannabis'* and that *'omitting important information*' (i.e. *'information on side-effects or the paucity of clinical evidence in relation to therapeutic treatments*') could lead to such sites being considered 'promotional' and therefore illegal.

Indeed, the 'guidance' goes so far as to state (p. 11)

> '*Material provided to patient support group members, either by businesses involved in medicinal cannabis or by a patient support group:*
> • *must not promote medicinal cannabis*
> • *must not encourage members to seek medicinal cannabis'*

and even (p 10):

> *'Referencing additional information (such as external websites and testimonials) that is promotional or endorses medicinal cannabis, may be considered advertising.'*

The rationale behind all this, claims the document, is that (p. 12):

> *The advertising and supply of medicinal cannabis has the potential to pose a significant public health risk.*

While warning:

> *There are criminal offences for advertising to the public unapproved therapeutic goods and therapeutic goods containing substances in Schedules 4 or 8 of the Poisons Standard (i.e. prescription medicines).*

Not unsurprisingly, such a seemingly draconian approach, while perfectly explicable in terms of EBM and the conventional regulatory regime's frames of reference, was met with hostility among advocates, and did little to restore any sort of 'shared moral order' between the TGA and those on the 'pro-cannabis side of the fence'.

Doctors Caught in the Crossfire

But just as advocates of both 'moderate' and 'radical' persuasions complain that the 'medical establishment' remains aloof, deaf and blind to their arguments and the need for compassion to be shown toward patients, so too do these same advocates appear dismissive and intolerant of the very real and quite defensible scepticism of those they see as heartlessly and unethically conspiring against them[43].

Between the stern and apparently uncompromising positions of 'establishment' organisations such as the TGA, AMA and the Royal Medical Colleges with their strict requirement for Evidence Based Medicine and the highly effective (if undisciplined) agitprop from patient advocacy groups, working doctors and healthcare professionals find themselves caught in the middle.

Doctors Surveyed
This is borne out by an important cross-sectional survey undertaken by Sydney University's Lambert Initiative published in 2018.

'Knowledge and attitudes of Australian general practitioners towards medicinal cannabis' (Karanges, Suraev et al BMJ Open Volume 8, Issue 7) discovered, among other things, that:

> *'The majority of GPs (61.5%) reported one or more patient enquiries about medicinal cannabis in the last three months. Most felt that their own knowledge was inadequate and only 28.8% felt comfortable discussing medicinal cannabis with patients.'*[44]

And concluded:

> *'The majority of GPs are supportive or neutral with regards to medicinal cannabis use. Our results highlight the need for improved training of GPs around medicinal cannabis, and the discrepancy between GP-preferred models of access and the current specialist-led models.'*[45]

Unintended Consequences
Such a situation is, we would argue, extremely unsatisfactory and one that has, quite predictably, had the knock-on effect of creating highly profitable businesses operating in some cases as little more than 'prescription mills' (some of the 'specialist' 'cannabis clinics') prepared to prescribe unapproved cannabis products quite freely. The result has been a slow but sure, though geographically patchy, rise in approval numbers nationally though not quickly enough to satisfy advocates and would-be consumers nor to make much of a dent in the black market but sufficiently conspicuous to galvanise the TGA into creating its new advertising and marketing guidance.

Equally, that organisation's 'Clinical Guidance Documents'[46] published in late 2017 too are limited in scope, relying entirely – as do respective Position Statements from the AMA and many of the Royal Colleges – only on the narrow evidence from randomised clinical trials.

Polarisation
We believe however that the extreme polarisation seen within the debate is unhelpful and ultimately damaging to everyone.

Patients and advocates are left feeling aggrieved, doctors remain ill- or under-informed while the 'medical establishment' runs the real risk of losing some of its political and moral legitimacy and/or credibility.

Desired Outcomes
Where medicinal cannabis use and availability in Australia are concerned, we believe a number of issues and possible objectives should be considered in any discussion, namely, among others:

- The need to put patient safety and well-being at the forefront of policy-making, education and treatment;
- The need to ensure the regulated market becomes the better and preferred option for patients (in terms of cost, product accessibility and product quality) than its currently far larger black-market counterpart;
- The need to empower healthcare practitioners with the best and most comprehensive knowledge available to enable genuinely informed sense- and decision-making;
- The need for *all* healthcare practitioners in Australia to be equipped with such knowledge and information;

- The need to safeguard and maintain the political and clinical legitimacy of regulators and healthcare providers.

Problems & Possible Solutions

We acknowledge problems exist with Australia's current regulatory system (illustrated by documents such as the Submission from United In Compassion[47] and others to the 2018-19 Statutory Review of the Narcotic Drugs Amendments[48] and no doubt many more to this current Inquiry) and that the system should be further harmonised between all States and Territories. We also assume price will become less of an issue when a domestic cannabis industry is finally able to introduce locally-sourced products to market, at commensurate or lower cost to patients currently using illicit ones.

Generally speaking therefore, the existing scheme is a functional one *if* those 'at the coalface' (i.e. doctors and other healthcare practitioners) are provided adequate information to carry out their day-to-day business.

Education is thus, in our view, the single most significant issue confronting all stakeholders within the current debate, with the strong caveat that to be truly effective, such education needs to be both science-based *and inclusive of a broader perspective than is currently officially sanctioned*.

Almost by definition therefore, this matter cannot and should not be entrusted to or delivered by any individual or organisation fully committed to and invested in a single epistemological position at the explicit exclusion of all others – something each of the 'three voices' within Gleeson's paper fall foul of.

Who Should/Should Not Deliver These?

Since, as the Lambert Initiative study suggested, many doctors appear more agnostic toward cannabis used medicinally than they do overtly hostile, so too should be the information with which they (the doctors) are presented and likewise the bodies that deliver it.

For this reason, organisations such as Australia's new Licensed Producers of cannabis products - known to be developing and propagating 'educational material' of their own on the subject - are eminently *unsuited* to doing so, as are advocacy groups and even the otherwise highly trusted Medical Colleges and any other bodies with a stated animus toward use of the drug.

Rather, organisations that take into account and represent the views and positions of *all* of the above are, we believe, best able to meet the challenge of providing material that is at once grounded in an ever-growing body of sound science and clinical expertise while acknowledging most of the products involved do not meet the strict standards of evaluation and regulatory endorsement of conventional medicines and should therefore be approached and deployed with due care.

Impartial, disinterested *and independent* organisations which are inclusive, reflective and above all *respectful* of the views of all 'voices' and operating without fear or favour toward any, would we believe, offer the most effective means of empowering healthcare practitioners with the necessary tools to hold informed discussion with their patients about use (or otherwise) of medicinal cannabis.

Recommendations

We therefore recommend in the first instance that polling similar to that undertaken by YouGov in the UK in respect of illicit use of cannabis and cannabis products be carried out in Australia to determine the extent of the issue domestically.

We further recommend all Health Departments in Australia endorse and explore the creation and, if necessary, the funding of a body or bodies as described in order to address issues laid out in this document and to help meet the objectives identified.

References/Footnotes

[1] See for example:
Medicinal cannabis in Australia: the missing links
Jennifer H Martin and Yvonne A Bonomo
Med J Aust 2016; 204 (10): . || doi: 10.5694/mja16.00234
https://www.mja.com.au/journal/2016/204/10/medicinal-cannabis-australia-missing-links

[2] Access To Cannabis For Medical And Scientific Purposes
Aust Gov 31st March 2016
Regulation Impact Statement – Department of Health
https://ris.pmc.gov.au/2016/03/31/access-cannabis-medical-and-scientific-purposes

[3]Explanatory Memoranda - NARCOTIC DRUGS AMENDMENT BILL 2016, Australasian LegalInformation Institute, Commonwealth of Australia
http://classic.austlii.edu.au/au/legis/cth/bill_em/ndab2016250/memo_0.html

[4] FreshLeaf's top ten 2020 trends for Australia's medical cannabis industry 02 Jan 2020
https://freshleafanalytics.com.au/freshleafs-top-ten-2020-trends-for-australias-medical-cannabis-industry/

[5] See:
Why so few Australians are using medicinal cannabis on prescription
Iain McGregor, Sydney Morning Herald October 10, 2017
https://www.smh.com.au/opinion/why-so-few-australians-are-using-medicinal-cannabis-on-prescription-20171008-gywqq7.html

[6] See:
Around 1.4M People In Britain Using 'Street Cannabis' To Treat Chronic Helath Conditions
The Independent, Monday 11 November 2019
https://www.independent.co.uk/life-style/health-and-families/cannabis-medicinal-uk-health-chronic-conditions-street-yougov-a9198081.html

[7] Review of the Narcotic Drugs Act 1967 - Final Report
Professor John McMillan AO
https://www.tga.gov.au/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967#report

[8] See for example:
Medical cannabis in Australia 'pretty much inaccessible', leaving patients looking to US
ABC 24 Jul 2018
https://www.abc.net.au/news/2018-07-23/medical-cannabis-patients-in-australia-look-to-united-states/10026308

[9] AMA on Medicinal Cannabis: Curiosity Over Medicnal Cannabis Grows But Not The Evidence
July 2018
https://ama.com.au/ausmed/curiosity-over-medicinal-cannabis-grows-not-evidence

[10] RACGP Position Statement on Medicinal Cannabis
https://www.racgp.org.au/advocacy/position-statements/view-all-position-statements/clinical-and-practice-management/medical-cannabis

[11] ANZCA/FPM Position Statement on Medicinal Cannabis
http://fpm.anzca.edu.au/documents/pm10-2018.pdf

[12] TGA Position Statement on Medicinal Cannabis
https://www.tga.gov.au/blogs/tga-topics/introduction-medicinal-cannabis-regulation-australia

[13] Penny Gleeson, 'The Challenge of Medicinal Cannabis to the Political Legitimacy of Therapeutic Goods Regulation in Australia' (2019) 43(2) Melbourne University Law Review (advance)
https://law.unimelb.edu.au/__data/assets/pdf_file/0010/3214864/Gleeson-432-Advance.pdf

[14] ibid.

[15] As glance through pages such as the below will testify
https://www.facebook.com/groups/mcuaa/

[16] For example see:
Lucy Haslam repulsed by medicinal cannabis laws, calls on nation to #FixDansLaw
https://www.northerndailyleader.com.au/story/5916875/repulsed-lucy-haslam-calls-on-nation-to-fight-to-fixdanslaw/

[17] Parliament of NSW: Public Inquiry - Medicinal Cannabis
https://www.parliament.nsw.gov.au/committees/inquiries/Pages/inquiry-details.aspx?pk=1999#undefined

[18] Victoria Public Inquiry - Medicinal Cannabis
Victorian Law Reform Commission October 2015
https://www.lawreform.vic.gov.au/all-projects/medicinal-cannabis

[19] Parliament of Tasmania: Public Inquiry - Medicinal Cannabis
http://www.parliament.tas.gov.au/ctee/Council/GovAdminA_LMC.htm

[20] Parliament of Queensland: Public Inquiry - Report No. 26, 55th Parliament – Public Health (Medicinal Cannabis) Bill 2016
https://www.parliament.qld.gov.au/work-of-committees/committees/HCDSDFVPC/inquiries/pastinquiries/PH-MedicinalCannibas-Bill2016

[21] ACT Public Inquiry - Medicinal Cannabis (unavailable on Internet)

[22] Parliament of Australia: Public Inquiry - Regulator of Medicinal Cannabis Bill
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill

[23] Caldicott et al, Medicinal Cannabis and the Tyranny of Distance: Policy Reform Required for Optimizing Patient and Health System Net Benefit in Australia
Appl Health Econ Health Policy (2018) 16:153–156
https://tinyurl.com/y88zylfg

[24] Sackett DL, Strauss SE, Richardson WS, et al. Evidence-Based medicine:how to practice and teach EBM. Second edition. Edinburgh:Churchill Livingstone, 2000
https://ebm.bmj.com/content/5/5/136

[25] Evide3nce-based medicine
Wikipedia
https://en.wikipedia.org/wiki/Evidence-based_medicine

[26] The volume of such information is too great to catalogue here. For exapmple Google returns 164,000 results for the search term 'medicnal cannabis observational studies'.

[27] See for example material provided by the International Association for Cannabinoid Medicines
https://www.cannabis-med.org/?lng=en

[28] Gleeson, P. ibid.

[29] See for example:
Medical cannabis can provide relief for people with terminal illnesses, where conventional drug treatment is ineffective and for those experiencing chronic pain. The Greens can be trusted to act compassionately and legalise medicinal cannabis.
https://greens.org.au/sites/greens.org.au/files/Greens%20Medical%20Cannabis%20Policy%20Initiative%20FINAL.pdf

[30] Labor Shadow Health Minister Catherine King's Response to Petition on Change.org website
https://www.change.org/p/decriminalise-the-use-of-medicinal-cannabis-for-people-with-terminal-cancer-like-my-son/responses/42198

[31] ibid.

[32] Justin Sinclair, An Open Letter to the TGA
21st August 2017
https://drive.google.com/open?id=1nB176-rUBm43ox2RhGAgBwG6GkamrKAm

[33] ibid.

[34] ibid.

[35] ibid.

[36] Cannabis industry and medical cannabis clinics need regulation, Meldon Kahan, MD CCFP FRCPC, Anita Srivastava, MD MSc CCFP, and Sarah Clarke, PhD
Canadian Family Physician
Can Fam Physician. 2019 Dec; 65(12): 864–868. PMCID: PMC6907381 PMID: 31831483
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6907381/#__ffn_sectitle

[37] See 60 Minutes Australia Poll
Facebook 4th August 2019
https://www.facebook.com/60Minutes9/posts/olivia-newton-john-and-her-husband-john-easterling-are-cannabis-converts-fightin/2255335191202450/

[38] Gleeson, P. idid.

[39] Gleeson, P. ibid.

[40] Gleeson, P. ibid.

[41] For a detailed explanation/discussion of this refer to podcast 'Wide Open Air Exchange' with Professor Nick Lintzeris
https://wideopenairexchange.com/2018/01/05/medical-cannabis-nick-lintzeris/

[42] Advertising guidance for businesses involved with medicinal cannabis products
Australian Govenment Department of Heatlh Therapeutic Goods Administration
https://www.tga.gov.au/publication/advertising-guidance-businesses-involved-medicinal-cannabis-products

Complying with therapeutic goods advertising requirements
Department of Health Therapeutic Goods Administration
https://www.tga.gov.au/medicinal-cannabis-guidance-document s

[43] See for e.g. Canberra Has Turned Its Back on Medicinal Cannabis Patients
Paul Gregoire, Sydney Criminal Lawyers website 11th September 2019
https://www.sydneycriminallawyers.com.au/blog/canberra-has-turned-its-back-on-medicinal-cannabis-patients/

[44] Knowledge and attitudes of Australian general practitioners towards medicinal cannabis, Karanges, Suraev et al
BMJ Open Volume 8, Issue 7
https://bmjopen.bmj.com/content/8/7/e022101

[45] ibid.

[46] Medicinal cannabis - guidance documents
Australian Govenment Department of Heatlh Therapeutic Goods Administration
https://www.tga.gov.au/medicinal-cannabis-guidance-documents

[47] United in Compassion Review of the Narcotic Drugs Act 1967 Submission to The Review
March 2019
https://www.odc.gov.au/sites/default/files/consultation-submission-review-narcotic-drugs-act-1967-uic.pdf

[48]Consultation: Review of Narcotic Drugs Act 1967 Consultation Documents
Australian Govenment Department of Heatlh Office of Drug Control
https://www.odc.gov.au/consultation-review-narcotic-drugs-act-1967#received