Public Consultation on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary to the Department of Health publishes herein all further valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard. These additional submissions were considered by the March 2016 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had their confidential information removed.

Materials claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out the Chapter 6 of the Scheduling Policy Framework for Medicines and Chemicals (SPF, 2015), issued by the Australian Health Ministers' Advisory Council. The SPF is accessible at https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals.

[redacted]

Subject: Proposed Amendments to the Poisons Standard - ACMS meeting, March 2016

Purpose

On 21 January 2016, the Therapeutic Goods Administration (TGA) sought comment from interested parties on proposed amendments to the Poisons Standard referred by the delegate for scheduling advice to the Advisory Committee on Medicines Scheduling (ACMS).

[redacted] is pleased to submit its comments on the proposal in relation to Cannabis and cannabinoids.

Summary Comment

[redacted] SUPPORTS the proposal to enable access to medicinal cannabis products by creating new Schedule 8 entries for Cannabis, botanically derived extracts (or derivatives) of cannabis, and Tetrahydrocannabinols (THC) as outlined in the invitation to comment.

In particular, [redacted] SUPPORTS the proposal to restrict access to a prescription or order of a state / territory authorised medical practitioner.

However, the policy should be written is such a way to not disrupt the existing production capability of the small but growing [redacted] industry; fibre, seed and intellectual property.

Background

Australia is a signatory to the United Nations Single Convention on Narcotic Drugs (1961), and Cannabis is currently included on Schedule IV of the Convention.

However, the intent of the Single Convention in relation to medicinal use of controlled drugs is clear.

The Preamble notes "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes".

Articles 1, 2, 4, 9, 12, 19, and 49 contain provisions relating to "medical and scientific" use of controlled substances. In almost all cases, parties are permitted to allow for dispensation and use of controlled substances under a prescription, subject to record-keeping requirements and other restrictions.

Global Trends

United States

In 1970, the US Congress placed marijuana in Schedule I of the Controlled Substances Act because they considered it to have "no accepted medical use." Since then, 23 of 50 US states and DC have legalized the medical use of marijuana.

tate	Year Passed	How Passed (Yes Vote)	Possession Limit
1. Alaska	1998	Ballot Measure 8 (58%)	1 oz usable; 6 plants (3 mature, 3 immature)
2. Arizona	2010	Proposition 203 (50.13%)	2.5 oz usable; 0-12 plants
3. California	1996	Proposition 215 (56%)	8 oz usable; 6 mature or 12 immature plants

4. Colorado	2000	Ballot Amendment 20 (54%)	2 oz usable; 6 plants (3 mature, 3 immature)
5. Connecticut	2012	House Bill 5389 (96-51 H, 21-13 S)	One-month supply (exact amount to be determined)
6. DC	2010	Amendment Act B18-622 (13-0 vote)	2 oz dried; limits on other forms to be determined
7. Delaware	2011	Senate Bill 17 (27-14 H, 17-4 S)	6 oz usable
8. Hawaii	2000	Senate Bill 862 (32-18 H; 13-12 S)	4 oz usable; 7 plants
9. Illinois	2013	House Bill 1 (61-57 H; 35-21 S)	2.5 ounces of usable cannabis during a period of 14 days
10. Maine	1999	Ballot Question 2 (61%)	2.5 oz usable; 6 plants
11. Maryland	2014	House Bill 881 (125-11 H; 44-2 S)	30-day supply, amount to be determined
12. Massachusetts	2012	Ballot Question 3 (63%)	60-day supply for personal medical use
13. Michigan	2008	Proposal 1 (63%)	2.5 oz usable; 12 plants
14. Minnesota	2014	Senate Bill 2470 (46-16 S; 89-40 H)	30-day supply of non-smokable marijuana
15. Montana	2004	Initiative 148 (62%)	1 oz usable; 4 plants (mature); 12 seedlings
16. Nevada	2000	Ballot Question 9 (65%)	2.5 oz usable; 12 plants
17. New Hampshire	2013	House Bill 573 (284-66 H; 18-6 S)	Two ounces of usable cannabis during a 10-day period
18. New Jersey	2010	Senate Bill 119 (48-14 H; 25-13 S)	2 oz usable
19. New Mexico	2007	Senate Bill 523 (36-31 H; 32-3 S)	6 oz usable; 16 plants (4 mature, 12 immature)
20. New York	2014	Assembly Bill 6357 (117-13 A; 49-10 S)	30-day supply non-smokable marijuana
21. Oregon	1998	Ballot Measure 67 (55%)	24 oz usable; 24 plants (6 mature, 18 immature)
22. Rhode Island	2006	Senate Bill 0710 (52-10 H; 33-1 S)	2.5 oz usable; 12 plants
23. Vermont	2004	Senate Bill 76 (22-7) HB 645 (82-59)	2 oz usable; 9 plants (2 mature, 7 immature)
24. Washington	1998	Initiative 692 (59%)	24 oz usable; 15 plants

Source: http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881

Other Countries

https://en.wikipedia.org/wiki/Legal_and_medical_status_of_cannabis - cite_note-8

- Austria - On 9 July 2008, the Austrian Parliament approved cannabis cultivation for scientific and medical uses.
- Canada - the regulation on access to cannabis for medical purposes, established by Health Canada in February 2000, defines two categories of patients eligible for access to medical cannabis. BC College of Physicians and Surgeons' recommendation, as well as the CMPA position, is that physicians may prescribe cannabis if they feel comfortable with it.

- France - As of 8 June 2013, cannabis derivatives can be used in France for the manufacture of medicinal products.

Clearly, other countries, which are also signatories to the UN Singles Convention are interoperating the convention with the intent in mind rather than simply the letter of the law. It is important that we acknowledge that the present knowledge of cannabis and its dangers as well as the benefits are much more advanced now than in the 1970's.

In General.
As stated above, [redacted] support the intent of the amendments. However, the proposal uses some terminology that would recommend be more precise. The rationale is that if some of the terms currently used are taken literally over the existing legislation confusion would be created and potentially interfere with legal research work presently in progress. The following is a list of suggested amendments to draft legislation.

1. Throughout the Paper it refers to *"Cannabis"* as if it were a drug. Cannabis is a plant species, of which the majority of the species is of no illicit drug value. In most cases the word Cannabis should be substituted for "*Cannabis resin*" or "*cannabinoids derived from cannabis*".

2. In a number of paragraphs it refers to "*cannabis products" or "Cannabis raw materials" and "supply of Cannabis based products" and "possession, sale or use of cannabis is prohibited*". This could equally mean hemp fibre, hemp cellulose, hemp seed oil and so forth. All products derived from industrial hemp (the majority of the cannabis species) are allowed under the UN singles convention. Therefore the proper use of the terminology in these cases would be; *"Cannabis resin" or "cannabinoids derived from cannabis*", and therefore not encompass the unintended industrial hemp products.

3. Later it states, "*Cannabis sativa (cannabis) is included as a prohibited substance under Schedule 9 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP*)". This is true when referring to the use as a drug but the UN Convention also specifically states in paragraph 2, article 28, "*This Convention should not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes."* For further information, observe the full text of the international drug control treaties obtained from the UN website at: http://www.odccp.org.

4. With regards to cultivation and production: *"Cultivation of cannabis carries a particularly high risk of diversion because the product can be readily used in its 'raw' state and is likely to be attractive to organised crime seeking to hide illegal activities under cover of a Commonwealth licence. The provisions in the Bill are designed to manage these risks."* This statement assumes that one needs to grow Marijuana Plantations to derive these medicines. To a large extent, the reality is the opposite of this statement. Most of the potential medicines come from non-drug plants (Industrial hemp). Industrial Hemp crops are currently grown in Australia under license and pose no risk to illegal activity as there is no psychoactive value in them. Furthermore, there are over 100 cannabinoids in the cannabis species and 99% of these cannabinoids are non-psychoactive.

   It should be noted that the biggest production of cannabis plants (Industrial hemp) grown in 2014 was 1,200 hectare by one grower in Europe, all used for medical cannabis. The straw was used for fibre in Automobile construction, the leaves and flowers contained 0.5% CBD and 0.07% THC. It was a safe crop as the levels were so low it had no value until processed and converted into a concentrated form. [redacted] point is that Industrial hemp can supply the products required at a much lower price than the highly intensive Marijuana Plantations and Industrial hemp is safe to grow.

[redacted]e fully support the need for the TGA to be involved to ensure any prescribed Cannabis Medicines are safe, registered and labelled correctly etc. However, I would like to make the following points for your consideration:

1. That the new TGA policy should not disrupt the existing production capability of the small but growing [redacted] industry: fibre, seed and intellectual property.
2. That the plant breeding and plant science aspects of our hemp industry should not be accidently caught up and adversely affected in any new policy or oversight. This plant science is core to Australia being a leader in the future IP of this industry.
3. That [redacted] industry experts be consulted as part of the final changes to policy.

[redacted]

4. That production of the desired cannabinoid molecules be allowed to be extracted from Industrial hemp crops safely and securely without the need for any additional or new grower or production legislation.

It is unfortunate that Medical Marijuana has attracted the level of attention that is has. As a result of this focus, the medical cannabis debate has been based around the THC molecule which has meant that we have been focusing on trying to work on adjusting to a legal framework when the solution is already in place via the legal, and already existing, industrial hemp industry. Therefore, it is not necessary to have Marijuana Plantations to supply the medicines needed.

[redacted] last point is that when the Health Minister speaks about hemp "sending a mixed message about the safety of cannabis" it stands to reason that by allowing Marijuana to be the source of Medicine, it sends an even more confusing "mixed message" and further adds to the confusion. I believe that it would be a far better proposition for the Health Minister to say "cannabis meds come from non-drug cannabis plants", i.e [redacted]. After all the greater proportion of the Australian public knows that there is a big difference between Marijuana and Industrial Hemp. This approach would then detract from the Marijuana prohibitionists' campaign who are, by default, presently able to twist the true message about the safety of their illicit drug.

[redacted]

Subject: Proposed Amendments to the Poisons Standards

[redacted]

The use of the specific technical and legal titles within any Policy or Legislation will be an important element to get the full and proper intention of the Policy or Laws relating to the subject. Given its history, the term Cannabis is very misunderstood and misused term within the industries that it is used.

For example, when one speaks of cannabis the majority of our population would relate this to the illicit drug, when in reality the term cannabis is a species of plant. What is even less understood, is that within the cannabis species, approximately 90% of the known sub-species of cannabis has no illicit drug value. This 90% is actually industrial hemp which has no narcotic or illicit drug value.

Bottom line. the common use for the plant material that has illicit drug value is Marijuana (to include other extracts such as Hash, Hash oil and so forth). Whereas the common uses for Industrial hemp include fibre, paper, rope and a very wide range of other constructive uses.

The challenge that we face in any legislation is that there is inevitably a cross over in interpretation and language that could limit or severely compromise existing legal and harmless business activities in another sector, unless definitions are specific and the desired intension is clear.

Due to the complex nature of this subject both botanically and legally, and decades of incorrect / inconsistent use of terminology I believe a Glossary of terms and definitions is required to be sure that the intended policy does not unwittingly have gaps or compromise adversely the unintended.

Please see my suggestions following.

The Plant
Cannabis sativa L: is the legal and taxonomic (botanical) name for the entire genus *Cannabis* species.

Cannabis sativa L, *Sub-species*: includes Industrial Hemp, Ditch weed and Marijuana etc. There are a number of wild types of cannabis, such as Ditch Weed, which have generally reverted from their bred state to a wild form. The overwhelming number of these reduce their THC content. However, domestication has been in process for over 1,000 years to create different end-uses such as fibre, seed and drug types. Presently most definitions of these sub-species types are based on the physical output (seed or fibre) and more importantly the chemical characteristics such as THC. It is worth noting that out of all the genetic seed banks of *Cannabis sativa* L globally, less than 10% of these sub-species have an illicit Drug value.

Cultivar : A plant variety that has been produced in cultivation by selective breeding

Industrial hemp: Legal commercial crops of cannabis grown and processed for it fibre and biomass. Also includes seed crops for planting seed and grain crops for seed oil. The delineation between industrial hemp and the illicit drug marijuana is based on the THC levels as a % of dry weight of the flowering head. This delineation point between hemp and illicit drug is not uniform and will vary by State and Country. But in general the range that delineates the two is anywhere between 0.3% to 1% THC or less of dry weight of flowering head. These cultivars not classified as a narcotic.

Marijuana: Plants of Cannabis that are grown as illicit drugs. Typically these plants have a THC of >6% in particular the flowering heads of female plants. Note that there is no illicit drug market for plants with lower than 6% as it is considered to be too low for recreational use.

Cannabinoid: There are over 100 different cannabinoids which include THC, THCA, CBD, CBDA, CBN, CBG, etc. These are chemical compound that primarily have an effect on cannabinoid receptors in the brain. Different cultivars have different levels and types of cannabinoids.

Phytocannabinoid: A cannabinoid synthesised within a plant, primarily in the trichomes of *Cannabis.*

Medicinal cannabis: Cannabis of any form cultivated with the intent to extract cannabinoids for medical or therapeutic purposes. This includes the use of legal Industrial hemp and the recreational drug Marijuana

Hemp seed oil, a vegetable oil derived from the seed. The seed of all types of cannabis plants do not contain any cannabinoids (although there may be minor contamination of cannabinoids on the seed hull due to proximity of the seed in relation to the trichomes when the seed is formed on the plant).

Cannabis essential oil, these are the terpenes produced by the plant and are the same as found in other plants such as Tea Tree terpenes.

Cannabis Cannabinoid resins, these are the crystal like trichomes formed on the cannabis plant and the source of medical cannabis molecules.

[redacted]

Submission to the Therapeutic Goods Administration Proposed amendments to the Poisons Standard - ACMS and ACCS meeting, March 2016

15 February 2016

[redacted]

Introduction

[redacted] welcome the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) proposed amendments to the Poisons Standard - ACMS and ACCS meeting, March 2016.

The focus of the comments, suggestions and recommendations provided in this submission are specifically on key areas that will impact on people affected by MS.

[redacted] response to the proposed amendments

There are currently 23,000 people living with MS across the country and this number is increasing. MS can be a particularly debilitating disease with an unpredictable disease course that affects people in different ways. For some it is a disease with periods of unpredictable relapse and remission. For others it is a progressive decline over time. For all, it is life changing.

As such, [redacted] together support any proven treatment that has been deemed safe by the Therapeutic Goods Administration and that helps to minimise the impact of the disease and allow people with MS to live more fulfilling lives.

The availability of medicinal cannabis-based products is a complex issue giving rise to an interesting debate that is currently occurring in a number of states across the country.

There are risks to consider with the availability of medicinal cannabis products. All medicinal products derived from cannabis require strict regulation and standardised doses of active ingredients, to ensure products are safe and effective, and can produce reliable effects with a controlled risk of adverse events.

Robust and reliable evidence is needed to determine the possible benefits and risks of cannabis-based products for managing symptoms of chronic illnesses such as MS. As part of any debate on this issue, [redacted] encourage the promotion of randomised controlled clinical trials to be conducted to determine the components, dosage and frequency of either cannabis or cannabis-based products and their efficacy and safety for managing a range of symptoms for people living with chronic conditions like MS.

A 2004 international survey of over 2,500 people with MS conducted by Australian researchers, indicated that around 10% of people with MS believed that cannabis was a factor that can help improve their MS symptoms.[1]

The most significant cannabis-derived product to have been studied for potential benefits in people with MS to date is the [redacted] (nabiximols). Its principal active cannabinoid components are the cannabinoids: tetrahydrocannabinol (THC) and cannabidiol (CBD). [redacted] is a mouth spray with proven benefits for muscle spasticity and motor control. Despite a licensing approval from the TGA for reducing spasticity in people with MS, [redacted] has not been. made available to people with MS in Australia due to the limitations of scheduling of cannabis-derived products.

As such, [redacted] would strongly support the inclusion of botanically derived extracts (or derivatives) of cannabis, and tetrahydrocannabinols (THC) where they are botanically derived from cannabis, as Schedule 8 entries, such that [redacted] can be made available in Australia under the current TGA approval for reducing spasticity in people with MS.

As the national peak bodies for people with MS in Australia we are passionate about affordable access to proven treatments that can improve the lives of people with MS. We are guided by the most up-to-date research and evidence-based recommendations to support the application of potential new therapies for MS symptom management. As such, MSA and MS Research Australia previously wrote to the PBAC secretariat in support of an application forinclusion of Sativex on the Pharmaceutical Benefits Scheme (PBS), although this application was not approved by the PBAC.

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[1] Simmons RD, Ponsonby AL, van der Mei IA, Sheridan P, *What affects your MS? Responses to an anonymous, Internet-based epidemiological survey*, Mult Scler. 2004 Apr;10(2):202-11.

Muscle spasticity is a significant problem for many people living with MS, affecting over 80% during the course of the disease and negatively impacting mobility and personal independence. Spasticity can cause pain, sleep disturbance and reduced mobility. These symptoms can significantly limit a person's quality of life as they have less energy, ability to complete everyday tasks and social activity. It can also lead to an increased reliance on carers and the health system if symptoms progress to a stage where mobility is significantly hampered or hospitalisation is required.

To date, available medications to treat spasticity for people with MS are not always effective and can have intolerable side effects. Sativex represents a potential new choice of symptom modifying therapy for people with MS who experience spasticity. To date, clinical trials of Sativex have indicated that it can reduce spasticity, pain and spasms and improve the quality of sleep.

Being able to better manage and limit the impact of spasticity would help give people with MS greater coordination and ability to complete everyday tasks which at times can be vital to maintaining self-esteem and a connection with family, friends and loved ones. It can also mean less time in hospital, meaning less strain on valuable medical and disability resources, which helps to reduce the economic impact of MS on society.

It is important to acknowledge that [redacted] does have side effects that will vary with each case. These can include dizziness, tiredness, depression, memory loss and nausea.

It is also worth noting that [redacted] is not a treatment to 'cure' MS, and while this treatment has clinical trial data and approval for spasticity, there may be other MS symptoms that may benefit from cannabis-based products which could be investigated in clinical trials.

[redacted] understand and acknowledge that people affected by MS will wish to investigate all options available to them to maintain their quality of life, whilst wanting the evidence-based reassurance that medications are safe, effective and affordable.

To this end, to facilitate safe and appropriate access to cannabis-based medications, we would be supportive of the additional option suggested, that access to be restricted to state/territory authorised medical practitioners. We would also welcome a regulatory framework that facilitates clinical trials for any new, unapproved cannabis-derived products to ensure that they can be tested for efficacy and safety within in a safe and supportive medical environment for patients.

Conclusion

Both [redacted] are committed to supporting the provision of proven therapies for improving the lives of people with MS.

As stated earlier, our position on these issues is guided by a scientific, evidence-based approach and we would advocate for a regulatory framework that will facilitate further clinical trials to determine the components, dosage and frequency of cannabis-based products and their effectiveness in managing a range of symptoms for people living with chronic conditions like MS.

We advocate for access, via authorised medication professionals, to approved, proven standardised formulations that have been clinically shown to be beneficial for specific medical needs (such as spasticity in MS where other medications are not effective or are contraindicated), while providing regulation that facilitates further research.

A regulatory framework that also ensures that the licensed manufacture of cannabis-based products results in quality-controlled products, with consistent components and concentrations would also facilitate the conduct of clinical trials. This would enable accurate data to be gathered on the safety and benefits of cannabis-based medications and allow accurate determination of which components of cannabis are most effective for specific symptoms and circumstances. This could lead to optimisation of medicinal effects and reduction of adverse effects and side-effects of cannabis use.

[redacted] would welcome licensed products such as Sativex being made available for people with MS in Australia, through the inclusion of botanically derived extracts (or derivatives) of cannabis, and tetrahydrocannabinols (THC) where they are botanically derived from cannabis, as Schedule 8 entries.

[redacted]

15th February 2016

Attention: Advisory Committee on Medicines Scheduling (ACMS)

Therapeutic Good Administration, Australian Government Department of Health

Email: medicines.scheduling@tga.gov.au

Submission regarding the proposed amendments to the Poisons Standard for cannabis and cannabinoids for ACMS meeting March 2016.

Dear Sir/Madam,

[redacted].

In general [redacted] strongly support the proposed amendment. It is likely that we will see an expansion in the use of cannabinoid products for therapeutic purposes in Australia in coming years – with a number of clinical trials being established using various GMP pharmaceutical grade cannabinoid products (including plant and extracts) across a number of conditions, and increasing applications for "compassionate access" to cannabinoid products through the Special Access Scheme and Authorised Prescriber pathways. In this context, the existing scheduling of cannabis based products for therapeutic use as S9 drugs is no longer appropriate.

Difficulties with S9 status for cannabis based products for therapeutic use

The current status of cannabinoid products as S9 drugs complicates their use as therapeutic products – and reflects an earlier era when cannabis based products were not considered as having any therapeutic potential. The emerging evidence regarding cannabinoid based products for a range of conditions (e.g. Whiting et al 2015; Deshpande et al 2015) indicates that in time we are likely to see an increasing range of cannabinoid products being used in medicine for a growing number of indications.

The current S9 status makes it very difficult for cannabinoid products to be used in clinical settings – essentially S9 drugs are considered 'illicit' substances, and this greatly complicates their therapeutic use, with uncertainty regarding how medicines are handled in pharmacy (storage, dispensing), prescribed by medical practitioners or used by patients. An example of the difficulties of the current S9 status of cannabinoid products is highlighted by current clinical trials in [redacted].

- There are three impending clinical trials (proposed to be CTN registered) using cannabinoid products – two using imported GMP grade cannabis flower / leaf products (one trial in palliative care settings, one trial examining performance in a driving simulator), and one trial examining an oral cannabis extract for chemotherapy induced nausea and vomiting.
- For all three trials, the existing scheduling of cannabinoid products as S9 means that the trials can only progress with specific [redacted] permission for the investigators (or their delegates) to possess these products, and to enable the investigators to effectively handle these as S8 medicines. This requires the clinician/researcher to complete an "Application for Authority to Possess Drugs of Addiction or Prohibited Substances for the Purpose of Research, Analysis, or Instruction", and then seek approval from the [redacted] enabling the clinician/researcher to possess these S9 drugs, and thereby comply with section 41 of the [redacted] and sections 10(2)(b) and 23(4)(b) of the Drug Misuse and Trafficking Act 1985. Our experience is that this process takes 2 to 4 weeks to complete the application and await approval from the Chief Pharmacist for each clinical site.

Whilst such 'work arounds' to the existing scheduling are possible for specific clinical trials conducted in one state, there are additional complexities for multisite trials across different states – requiring different regulatory procedures according to each jurisdiction. Furthermore, this administrative step of having to apply to state governments for special authority places considerable administrative hurdles for clinicians and patients using alternative pathways for accessing unlicensed therapeutic products (e.g. such as Special Access Scheme, Authorised Prescribers), and this is likely to serve as yet another barrier to accessing cannabinoid medicines.

Ultimately, whilst each jurisdiction has the ability to develop 'work arounds' to the existing S9 scheduling – such an approach risks the development of a patchwork regulatory framework across different jurisdictions – whereas this proposed amendment provides the basis for much preferred national framework.

Is S8 an appropriate schedule for cannabinoid products?

It is entirely appropriate that cannabis-based products designed for therapeutic use are rescheduled as S8 drugs (e.g. for THC), or in some cases S4 (e.g. for cannabidiol (CBD)). The framework for S8 drugs – currently applied to other psychoactive drugs with the potential for abuse - such as opioids, amphetamines and some benzodiazpeines (e.g. alprazolam, flunitrazepam) – provides a suitable level of oversight and safety for the handling of these medicines, without unnecessarily restricting their use

where clinically appropriate. The cannabinoids generally pose a considerably lower risk of toxicity or abuse than existing S8 drugs such as opioids or amphetamines.

It is important to emphasise that there are at least 106 different cannabinoids in the cannabis plant and most cannabinoids other than THC have no or minimal psychoactive effects, and have minimal risk of misuse (Arnold et al 2016). One such example is CBD – which is being considered as a medication for treatment-resistant epilepsy– amongst other conditions (Devinsky et al 2014). This was recently rescheduled in Australia as an S4 drug – and in time, we believe many of the other non-psychoactive cannabinoids should follow this path. Until then, an S8 scheduling at least enables greater clarity on using these as therapeutic products.

Recommended improvements to the amendment

There are a number of improvements that we would like to propose to the amendment.

1. The proposed amendment refers specifically to "Tetrahydrocannabinols (THC) where they are botanically derived from cannabis", and whilst THC continues to be an important cannabinoid for therapeutic purposes, we are likely to see a range of other cannabinoid molecules (e.g. CBDV, CBDA) being developed as therapeutic products in the near future, with several of these cannabinoids already being used in clinical trials internationally. Hence, we propose that the amendment expand the range of plant-derived cannabinoids beyond THC to include all plant-derived cannabinoids. We recognise that in time many of these cannabinoids may eventually be rescheduled to S4 status (as per CBD) as they are not psychoactive. However in the interim we would like to ensure that they also are considered S8 drugs when used therapeutically.

2. The amendment only includes cannabinoids for therapeutic purposes – and the current proposed amendment does not appear to include cannabis based products for use in preclinical research that might involve plant chemistry, or testing cannabinoids in cellular and animal models of disease. Preclinical research is important and often provides a necessary step in the development of new therapies. [redacted] current reading of this amendment excludes cannabis products used for preclinical research purposes. [redacted] recommend that the amendment also extends S8 status to cannabis-based products used in research by legitimate researchers (e.g. Universities, private research laboratories, Institutes). Failure to include cannabis based products for preclinical research would mean that the existing barriers to preclinical research will continue which would stifle innovation in this rapidly developing area of therapeutic development. An example is that whilst CBD has recently been scheduled as an S4 for therapeutic purposes, researchers have to continue to handle it as an S9 drug for preclinical research. This is an unnecessary barrier to Australian scientific progress in this field.

3. The extension of S8 status to a cannabis based product should also bring it within scope for application under Special Access Scheme Category A (SAS-A). At present S9 drugs are excluded for consideration under SAS-A. [redacted] would strongly recommend that the amendment ensures that where a cannabis product for therapeutic purposes is scheduled as a S8 drug, that it then becomes eligible for consideration under SAS-A (as the current proposal appears to restrict supply to Category B using appendix D or the SUSMP despite rescheduling of therapeutic products).

Summary

In summary, [redacted] strongly support the proposed amendment, and consider it a necessary step towards the development and utilisation of cannabis based medicines in Australia. The proposed rescheduling

will considerably simplify the mechanisms by which cannabis based products can be used for therapeutic purposes, and provides a national framework thereby avoiding the possibility of different jurisdictions creating different and contradictory 'solutions' to their existing S9 status. [redacted] also make several recommendations regarding how the amendment can be improved.

[redacted] welcome the opportunity to provide more information or address any queries of the committee. Please do not hesitate to contact either me [redacted] if you have any queries or concerns regarding our submission.

Yours Sincerely

[redacted]

References

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Devinsky O, Cilio MR, Cross H, Fernandez-Ruiz J, French J, Hill C, et al 2014 Cannabidiol: pharmacology and potential therapeutic role in epilepsy and other neuropsychiatric disorders. Epilepsia 55(6):791-802.

Arnold, J.C., D. Allsop, N. Lintzeris, and I.S. McGregor, Pharmacological actions and associated therapeutic levels of phytocannabinoids: an evidence check review brokered by the Sax Institute (www.saxinstitute.org.au) for the NSW Ministry of Health, 2016, Sax Institute: Sydney, Australia.

Please spend the time to peruse my submission to the Impact Statement, along with my thoughts, from [redacted]

1/ In addressing this clause , I personally do not agree with the proposal s9 to s8, as I cannot accept that cannabis is a narcotic drug & feel it should not be restricted in any way & suggest it's removal from the narcotic substance list, & reclassified as a medicinal herb

2/ [redacted] used cannabis throughout this period & found efficacy in this product & has been [redacted] preferred medicine

[redacted]

Due to the continuous annual police raids & destruction of [redacted] necessary to [redacted] grow & make [redacted] medicine [redacted] assurance of supply & quality. & feel that appropriate access, (sect 1- access for this medicine) is necessary, should be allowed to grow in every garden in Australia, for it's nutritional value as well as a medicine.

[redacted]

It is an extremely safe, natural, medicinal herb..

[redacted]

The law needs to change..

[redacted]

Regards,

[redacted]

Thank you for allowing me the opportunity to contribute to your call for submissions into the rescheduling of Cannabis from S9 to S8

[redacted] These toxic and potentially deadly pharmaceutical medications, effect me quite badly, with both physical & long lasting and detrimental, psychological side effects. Cannabis is neither toxic nor lethal and gives me relief without depriving me of quality of life. Quality of life, which is so badly compromised with prescription medications.

Further to this, [redacted]

Cannabis is a food and will never be successfully made into a pill form. That's like putting eggs and flour only in, making a batter and saying “that's a cake, there you go”. You don't have all the necessary Entourage 'ingredients' without whole plant medicine. You can't just take a Cannabinoid here and a terpene there, slap them in a pill and say that it is Cannabis Medicine because it isn't. Just as eggs and flour alone don't make a cake!

[redacted]

[redacted] Cannabis Assisted with pain relief, and was instrumental in getting [redacted] off [redacted], with NO SIDE EFFECTS OR WITHDRAWAL SYMPTOMS [redacted] n. Hemp seeds have been shown in studies to have the potential to rewrite damaged DNA back to its original form. [redacted] Not decarboxylated so no psychoactive effects but brilliant results for skin lesions and acute itching, joint pain relief if rubbed into joints is also noticeable. [redacted]

[redacted] Rather, mask symptoms only and giving the pharmaceutical companies an ongoing customer, slowly declining in health and deprived of the basic human right, of effective healthcare choices.

[redacted] have also found that they require specific strains for most effective treatment. Just as with 6 different varieties of Red Roses, each has their own individual scent, composition and the persons smelling, own individual taste and personal and individual, bodily requirements which will make one rose more attractive/enticing/suitable whilst another, although still as sweet and appealing, does attract ones' own individual taste to a specific rose which is more appealing to that individual. The same applies with wines, you could have 6 different Chardonnay's, each of similar composition & quality, but you will be drawn more to one than another through personal choice and taste. Cannabis is no different and should really be classed as a herbal complimentary medicine, as a botanical, which is what it is. Personal appeal to various strains is not only vital, it gives most effective treatment results.

[redacted]

[redacted]

Rescheduling of Cannabis will allow for accurate education regarding Cannabis Medicine and the Cannabis patient, where now there is only ignorance, personal judgements and bigotry and uninformed opinions of medical staff, abhorrent bedside manner and abuse of basic human rights, as [redacted] was forced to endure. An official complaint has been placed with [redacted]. Doctors do not treat diseases anymore. They type a disease or group of symptoms into a pharmaceutical program or look up a MIMS type publication and a list of prescription choices are given. [redacted] Some being honest and admitting they know nothing save the name! That's scary! Pharmaceutical companies romance Doctors with luncheons, holidays, gifts and more. Do not deny this, as [redacted]. Both public & private. The deplorable Emergency Department treatment by staff, will no longer be an issue once Cannabis Medicine is legally available and educated and informed opinions replace the nonsense hospital and medical staff spruke now in their uninformed & ignorant Cannabis Medicine dialogue I am without doubt, [redacted] can be controlled if not eliminated with Cannabis medicine and appropriate dietary protocols.

In closing, unless the public are given adequate strain selection for their conditions, you will still have so very many, who need to illegally heal themselves due to inadequate choice options. [redacted] DEFY attitude that [redacted] Cannabis patients now have and will fight for [redacted] need of specific strains & personal treatment methods required to treat [redacted], with effective and safe medications through ANY court. This is [redacted] BASIC HUMAN RIGHT

Thank you
[redacted]

[redacted]

Proposed Amendments to Poisons Standard –ACMS meeting, March 2016

Comments by [redacted] to the proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling

Cannabis and Cannabinoids – New Schedule 8 entry

February 2016

[redacted]

CANNABIS & CANNABINIODS

Proposal to enable appropriate access to medicinal cannabis products by creating new Schedule 8 entries for the following substances for internal human therapeutic use:

- *Cannabis (plant and flowering tops),*
- *Botanically derived extracts (or derivatives) of cannabis, and*
- *Tetrahydrocannabinols (THC) where they are botanically derived from cannabis.*

including when prepared or packed for therapeutic use, and where the substances:

- *have been produced or manufactured in accordance with the Narcotic Drugs Act 1967; or*
- *have been imported in accordance with the Customs (Prohibited Imports) Regulations 1956.*

***except** when included elsewhere in Schedule 8 or Schedule 4.*

Cannabis and THC would remain Schedule 9 substances:

- *for human therapeutic use when it does not fit the above criteria, or*
- *when not for human therapeutic use, or*
- *does not fit any other current exceptions.*

Options for additional controls on these substances through an entry in Appendix D of the SUSMP could include one of the following:

- *restriction of access to state/territory authorised medical practitioners (current Item 1 - Poisons available only from or on the prescription or order of an authorised medical practitioner); or*
- *restricting access to: clinical trials conducted under the TG Act when unapproved products including these substances are used i.e. Clinical trial Notification (CTN) or Clinical Trial Exemption (CTX); and*
- *supply as an unapproved product through the TGA Special Access Scheme Category B or the Authorised Prescriber scheme similar to the current Item 3 (Poisons available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health under section 19 of the Therapeutic Goods Act 1989.); or*
- *restricting access by creating an entry such as "Poisons available only from or on the order of a specialist physician"*

[redacted] supports the medicinal use of cannabis preparations, following the appropriate processes through Australia's regulatory bodies, and believes that the appropriate classification in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for cannabis and cannabinoids for therapeutic use is Schedule 8.

[redacted] also believes cannabis and cannabinoids should be listed in Appendix D, paragraph 3 which would require a medical practitioner to obtain authorisation by the Secretary of the Commonwealth Department of Health in order prescribe this substance to patients. This would be consistent with the scheduling status of dronabinol, another cannabis derivative. Alternatively, restricting access by creating an entry such as "Poisons available only from or on the order of a specialist physician" could also be considered.

The risk and benefits of the use of the substance[1]

A number of potential therapeutic uses of cannabis and its derivatives have been identified from pre-clinical investigations. Possible clinical indications include treatment for spasticity and pain in multiple sclerosis, cancer associated nausea and vomiting, cancer pain and HIV neuropathy.[2] Despite its

[1] Section 52E(1a)- *Therapeutic Goods Act 1989*
[2] Murnion Bridin, Medicinal Cannabis NPS MedicineWISE in MIMS matters-Summer 2015

[redacted]

therapeutic potential evidence is currently limited and current media reports citing the apparent efficacy of medicinal cannabis are likely to reflect subjective or anecdotal reports rather than objective outcomes.

Creating a new Schedule 8 entry for cannabis and cannabinoids would make it easier for researchers to conduct human clinical trials to better establish the risk profile and establish clinical guidelines in relation to optimal dosing, frequency, indications and specific preparation. This is particularly important as it can be difficult in some jurisdictions to gain access to Schedule 9 substances, even for medical purposes.

[redacted] notes that the NSW Government announced in September 2014 that a Working Group would be formed to initiate a clinical trial for medical cannabis. The trial would explore how cannabis could provide relief for patients suffering from debilitating or terminal illnesses.[3] The NSW Government will also be taking the lead in an upcoming cross-jurisdictional trial and this scheduling amendment will enable greater accessibility of cannabis for this purpose. The Queensland Government announced it will partner with the NSW government in trailing medicinal cannabis from 2016.[4] The Victorian Government recently accounted it would legalise access to locally manufactured cannabis products for use in exceptional circumstance from 2017.[5]

The various restrictions that relate to Schedule 8 medicines, provide a safeguard against abuse and misuse of this substance.

The purposes for which a substance is to be used and the extent of use of a substance[6]

Given the limited evidence base (compared to other medicines) and the fact cannabis may be prescribed for symptoms of serious conditions, [redacted] believes medicinal cannabis should only prescribed in cases where patients are not responding to treatments and/or medicines which have a more established efficacy and risk profile.

[redacted] therefore supports additional restrictions on the ability to prescribe medicinal cannabis, particularly as there are few TGA registered medicinal cannabis products currently available. Suitable restrictions may include:

- Listing cannabis and cannabinoids in Appendix D, paragraph 3 which would require a medical practitioner to obtain authorisation by the Secretary of the Commonwealth Department of Health in order prescribe this substance to patients. This would be consistent with the scheduling status of dronabinol, another cannabis derivatives.
- Restricting access by creating an entry such as "Poisons available only from or on the order of a specialist physician"

Summary

[redacted] supports a Schedule 8 listing for cannabis and cannabinoids combined with additional restrictions on prescribing through listing the substances on Appendix D paragraph 3 or stipulating the poisons are only available on the order of a specialist physician.

[3] http://www.nsw.gov.au/news/medical-cannabis-trial
[4] https://www.qld.gov.au/health/conditions/all/clinical-trials/medicinal-cannabis/index.html
[5] http://www.premier.vic.gov.au/medicinal-cannabis-to-be-legalised-in-victoria/
[6] Section 52E(1a)- *Therapeutic Goods Act 1989*

[redacted]

[redacted]

Medicines Scheduling Secretariat
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Secretariat

Thank you for the opportunity to contribute to the consultation regarding the proposed amendments to the Poisons Standard. In particular, this submission addresses the proposal to amend the scheduling of cannabis and cannabinoids in Schedule 8.

I write to provide information about the Victorian Government's *Access to Medicinal Cannabis Bill 2015* and the approach taken in the Bill to classification of medicinal cannabis. Please note this submission is for information only and does not preclude the Victorian member of the Advisory Committee on Medicine Scheduling participating in the discussion of the proposal at the upcoming meeting.

The *Access to Medicinal Cannabis Bill 2015 (Vic)* was introduced into the Victorian Parliament on 8 December 2015 and establishes a legal framework for the cultivation, manufacture and provision of medicinal cannabis for patients in exceptional circumstances. The scheme will provide access to a quality-controlled, regulated product with careful clinical oversight.

The Victorian Bill is based on the recommendations of the Victorian Law Reform Commission's (VLRC) Final Report on Medicinal Cannabis released in August 2015. As suggested in the Commission's report the Bill removes authorised cannabis products from the definition of a 'Schedule 9 Poison' for the purposes of the *Drugs and Controlled Substances Act 1981* (Vic) and the associated regulations. Instead, a new class of poison has been introduced into the Act: 'medicinal cannabis'. Unauthorized cannabis will continue to be prohibited as a "drug of dependence".

This will enable appropriate controls to be applied to authorised medicinal cannabis under the new legislation and associated regulations. In Victoria's view the existing frameworks for control of Schedule 9 substances were not suitable for this purpose and we have the same view regarding existing Schedule 8 controls.

The Victorian Government has decided that access to medicinal cannabis requires the comprehensive framework recommended by the VLRC and adopted in the *Access to Medicinal Cannabis Bill 2015*. This framework will, for example:

- Enable only specialist medical practitioners to authorise patient access
- Define eligible patient groups and provide a process for expert review of eligibility

[redacted]

- Establish monitoring and oversight by an Office of Medicinal Cannabis

I note that under section 18 of the *Therapeutic Goods Act 1989 (Cth)* the proposed rescheduling would enable any medical practitioner to supply cannabis and cannabis extracts to Category A patients (in life threatening situations) by notification to the TGA. This was not possible under schedule 9. For jurisdictions without specific controls for medicinal cannabis of the type in the Victorian Bill this may lead to problems with overprescribing or inappropriate prescribing.

Victoria is also concerned to ensure that the Special Access scheme will not be available as an alternative path for medical practitioners and patients who are not authorised under the Victorian scheme to access products that have not been approved for use in Victoria.

Thanks you again for the opportunity to provide this submission.

Yours sincerely

[redacted]

[redacted]

FEB 2016

SUBMISSION TO
The Advisory Committee on Medicines Scheduling (ACMS)
& The Advisory Committee Chemicals Scheduling (ACCS)

Commenting on the proposal to enable appropriate access to medicinal cannabis products by creating new Schedule 8 entries for the substances listed for internal human therapeutic use; and Cannabis and THC would remain Schedule 9 substances....when not for human therapeutic use..

INTRODUCTION

[redacted]

Many have tried all manner of pharmaceutical preparations that have proven dangerous, leading to impairment and inability to function in the workplace or on the roads. Others have had allergic reactions to these chemically manufactured preparations causing devastating physical and mental side effects that substantially reduce their quality of life.

Conventional medicine has let them down and all are searching for alternatives. The majority are finding exceptional relief and extremely valuable therapy from illegal whole-plant cannabis extractions.

For them "appropriate access" is access to the strain best suited tho their condition that is affordable, safe and reliable. This is be a fundamental human right. To prosecute and punish people who are DISABLED by their conditions, for seeking relief from their ailments, is a crime against the humanity and discrimination against the disabled .

Now that the draft legislation has been tabled federally to change the Narcotics Act, [redacted] understand the reasons for this proposal and we also understand that our time is probably wasted in preparing this document, but [redacted] and the general public are the end STAKEHOLDERs in this issue and they want "appropriate access".

[redacted] **does not support the amendments**

Cannabis is not a poison and has no place being on the poison schedule.
History shows us that "prohibiting access" to it was the brain child of a US campaign to slur its reputation with the public because of vested financial interests in other places.
Prior to this, Cannabis was a respected medicine and doctors used it freely and often. It was included in many over the counter preparations and was trusted as being safe and effective.
WHAT changed?
The plant and its compounds remain the same. The law made it a poison.
Now its time for the lawmakers to undo the lies and deceit.

Antidotes. Empty stomach by emetic or gastric lavage. Stimulants, such as strong black coffee, frequently. Strychnine, ½ gr., hypodermically. Keep patient warm. Artificial respiration may be necessary.
Toxic Effects. Doses of 2 grains or more, whether ingested or smoked, cause euphoria, mental confusion, hallucinations and motor excitement. The initial phase of inebriation is succeeded by irritability and somnolence, and after some hours by a comatose sleep. Toxic doses cause vertigo and collapse but serious poisoning is rare, as the margin between the effective and the fatal dose is wide. Addiction does not give rise to serious physical consequences and, except in severe cases, withdrawal symptoms are insignificant. Continued use of the drug may lead to mental deterioration but insanity is a rare sequel.
The physiological activity of the hemp-plant varies with the locality in which it is grown. The minimum fatal dose by the mouth of charas, ganjah and bhang works out at 2000 mg., 8000 mg. and 10,000 mg. per kg. body weight respectively.—R. N. Chopra and G. S. Chopra, "The present position of hemp-drug addiction in India", *Indian med. Res. Mem.*, No. 31, July 1939, 1-119.

The minimum fatal dose by mouth is [redacted] of body weight. (RN Chopra)
CHOPRA, R. N.; CHOPRA, G. S.: The Present Position of Hemp-Drug Addiction in India (a pamphlet) Indian Medical Research Memorandum No. 31, Calcutta, 1939, pages 1-119

According to Francis L. Young Administrative Law Judge (DEA) *Dated: SEP 6 1988*

> *4. Nearly all medicines have toxic, potentially lethal effects. But marijuana is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.*
>
> *5. This is a remarkable statement. First, the record on marijuana encompasses 5,000 years of human experience. Second, marijuana is now used daily by enormous numbers of people throughout the world. Estimates suggest that from twenty million to fifty million Americans routinely, albeit illegally, smoke marijuana* ***without the benefit of direct medical supervision.*** *Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply* ***no credible medical reports to suggest that consuming marijuana has caused a single death.***
>
> *15. In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death.*
>
> *16. Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care.*
>
> *Dated: SEP 6 1988* http://druglibrary.org/schaffer/library/studies/young/young4.html

Its toxicity remains unaltered.

The toxicity of synthetically produced competition:
Many of our most commonly used drugs, from painkillers to antidepressants, are dangerous and are killing us off in large numbers, says a leading researcher visiting Australia next week.

Peter Gotzsche, a co-founder of the Cochrane Collaboration, the world's foremost body in assessing medical evidence, arrives in Australia on Monday for a whirlwind speaking tour warning Australians about their use of prescription medications. He estimates that 100,000 people in the United States alone die each year from the side-effects of correctly used drugs.

http://www.smh.com.au/national/health/peter-gotzsche-founder-of-the-cochrane-collaboration-visits-australia-to-talk-about-dangers-of-prescription-drugs-20150204-136nqc.html#ixzz408mdq2H5

"Few know that systematic reviews of hospital charts found that even properly prescribed drugs (aside from misprescribing, overdosing, or self-prescribing) cause about 1.9 million hospitalisations a year. Another 840,000 hospitalised patients are given drugs that cause serious adverse reactions for a total of 2.74 million serious adverse drug reactions. About 128,000 people die from drugs prescribed to them. This makes prescription drugs a major health risk, ranking 4th with stroke as a leading cause of death."
http://ethics harvard.edu/blog/new-prescription-drugs-major-health-risk-few-offsetting-advantages

Number of hospitalisations due to cannabis?
Current use - In 2013, it was estimated about 6.6 million (or 35%) people aged 14 or older had used cannabis in their lifetime and about **1.9 million** (or 10.2%) had used cannabis in the previous 12 months. http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129549848

In 2014 there were **5254** cannabis related hospitalisations Australia wide.
http://www.aihw.gov.au/alcohol-and-other-drugs/aodts/drug-related-hospitalisations/

Number of deaths due to cannabis? Nil

What is appropriate access ?

1. it is access that is affordable and available to EVERYONE who can benefit from its use;
2. it is access to the raw fresh product and its preventative, as much as it curative properties;
3. it is access for all varieties that are condition specific and the entourage effect;
4. it is access to whole-plant cannabis and cannabis products without having to jump through bureaucratic hoops or unravel miles of the red tape;
5. is access to home growing which ensures patient safety, and a reliable ongoing supply; and knowing exactly what is being used in the whole process from growing to extraction;
6. it is going out into your own garden and picking leaves to put into your food without fear of being visited by police, having your medicine destroyed, and being fined and/or convicted
7. it is access that allows patients to grow and share their crop with others suffering similar conditions via a compassionate network;
8. appropriate access is UNRESTIRCTED access. Even in America cannabis is not available solely on prescription but on recommendation by a doctor.

The greatest concerns to current users of the natural product, is the **potential cost and quality** of any pharmaceutical/government controlled supply.

Users want reassurance that it will be the variety bred for, and most relevant for their condition. (eg 'Blue Cheese' for liver cancer). Research and anecdotal evidence is finding that different strains of cannabis provide the best relief for particular symptoms and conditions, so Sativex, Epidolix, CBD only and similar products are unlikely to benefit **every patient who currently benefits** (or could benefit) from appropriate access to the entourage effect of whole plant natural therapies.

Single cannabinoids or synthetic copies are incapable of the same results and are expensive to produce and buy.

Currently [redacted] is not subsidised by the PBS; costs around $800 month and is only available to MS patients. This puts it out of reach for those who most need it and who are probably on a disability pension. If it were subsidised it would cost the tax payer around $794 per month, for something that can be grown for the cost of a tomato plant.

How many decades of expensive trials lay ahead for each condition that cannabis can treat,cure prevent and relieve NOW? We need to speed the process up.

Purchasing from the black market is also cost prohibitive. Home growing puts canna-meds well within the financial reach of every person who needs it.

People will continue to seek out and buy black market supplies regardless of any changes you might make to the scheduling 'detail' thus opening themselves up to black market profiteers and their unscrupulous practices such as using illegal, cancer causing plant growth regulators (PGRs). *Please see attached pdf file for details.*

People need safe and affordable access now. Home growing is the answer.

Any regulatory blockades should be kept for big pharmaceutical companies and applicants who would be selling to the public; while users who grow their own, should be free from user pays fees. It is our legislated right to have access to affordable, SAFE and effective medicine. And cannabis grown in the garden can achieve this without red tape and hoop jumping for people who are suffering or terminally ill with no other hope on the horizon.

Suggested alternatives

GRAPE MODEL
Treat Cannabis/Hemp like grapes,
You can grow as many grapes as you want, no license.
You can make as many of those grapes as you want into wine, no license.
You can share that wine with your friends and family, no license.
HOWEVER the moment you want to sell some of that wine you require a license and to show quality control and safety for human consumption.
This way the supply problem addressed and the tax on commercial sales will help balance the budget.

Remove all the natural cannabis products in this TGA proposal from the poison schedule altogether. **Re classify cannabis and cannabis products as a botanical ingredient within complimentary medicine**. Governed by the manufacturing legalisation. It is an ingredient. It is a plant. It is non

toxic. It can be applied in many ways (ingest, vaporise, suppositories, pessaries, topical).

Keep the stringent rules for large scale operations and profit making concerns who will supply to the government. People who wish to grow and use should be able to do so at will. Restricted access and trials need to be in place for synthetic versions of cannabis because their safety and efficacy is UNKNOWN. Herbal products that have documented proof over 5000 yrs do not need trials or vigorous testing.

The anti cannabis campaigners say this would put our kids at risk of harm. Kids are always going to want to experiment with mind altering substances. Be it booze, prescription medication, street drugs, glue or cleaning products. Is it not best to have a healthy alternative available for them that. As with the other recreational drug (booze), parents need to educate themselves and their kids about its use.

> 5TH FEBRUARY 2016: *HILLS teenagers are risking death in **a bid to get a high** from aerosol cans in a dangerous practice called **"huffing"**..Hills Local Area Commander Supt Rob Critchlow said: "The practice of 'huffing' or inhaling volatile chemicals is so dangerous it is mind-boggling anyone would do it."... seizures and blackouts, chest pains and irregular heartbeat....Abusers can get addicted and it can cause long-term brain damage.*
> http://www.dailytelegraph.com.au/news/national/teens-risk-death-huffing-cans-of-deodorant/news-story/c6a90e4afcd93938da37123d6f5dd27d

Penalties should be removed for possession and cultivation and new laws put in place for prosecuting sellers to make a profit without adhering to legitimate business requirements and practices - eg ABN, growers licence or manufacturing licence, GST could be collected on recreational sales.

Most people these days are aware of the potential of cannabis medicine. [redacted] is fielding increasing requests every day from desperate people clawing for access – many are afraid to try it for fear of prosecution. This is indeed a sad situation.

Every poll conducted in the media for the last 2 yrs has returned an average of 96% of the population agreeing that cannabis should be legal for medical use.

What do you see as the likely benefits or costs of this proposal ?

THERE ARE NO BENEFITS to the end stakeholders. It gives big business (pharmaceutical companies) a strangle hold on cannabis. It perpetuates the myth that cannabis is dangerous when in fact it is the most beneficial **food** on the planet.

The REAL COST in $ terms of these restrictions will be to the taxpayers of this country who will continue to subsidise an aging population, the soaring cost of health services and PBS subsidies for drugs that don't work as well as cannabis. Full and free access to cannabis could save Medicare from going down the gurlger and save Australians from a US style of health care.

These costs could be wound back considerably in the future if cannabis and hemp seed foods were to be freely available NOW – the savings would be phenomenal with a few short years. Conditions like chronic pain; mental health; epilepsy; glaucoma; Parkinson's and Alzehimers; cancer; hepatitis C and autoimmune diseases can be treated with home grown cannabis. The savings on the PBS alone could pay the welfare budget!