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.

45. Ellingson LD, Shields MR, Stegner AJ, Cook DB. Physical activity, sustained sedentary behavior and pain modulation in women with fibromyalgia. J Pain 2012; 13: 195-206

46. Seaman DR. The diet induced proinflammatory state: a cause of chronic pain and other degenerative diseases? J Manipulative Physiol Ther 2002; 25: 168-179

47. Eisenberger NI, Lieberman MD, Williams KD. Does rejection hurt? An fMRI study of social exclusion. Science 2003; 302: 290-292

48. Eisenberger NI. The neural bases of social pain: evidence for shared representations with physical pain. Psychosom Med 2012; 74:126-135

49. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. Gen Hosp Psychiatry 1982;4: 33-47

50. Dowd H, Hogan MJ, McGuire BE, Davis M, Sarma KM, Fish RA et al. Comparison of an Online Mindfulness-based Cognitive Therapy Intervention with Online Pain Management Psychoeducation: A Randomized Controlled Study.Clin J Pain. 2015 Jan 6. [Epub ahead of print]

51. Chiesa A, Serretti A. Mindfulness-based interventions for chronic pain: a systematic review of the evidence. J Altern Complement Med. 2011 Jan;17(1):83-93. doi: 10.1089/acm.2009.0546.

52. Broom B. Meaning-full disease. London: Karnac Books; 2007

53. Hsu M, Schubiner H. Recovery from chro¬nic musculoskeletal pain with psychodynamic consultation and brief intervention: a report of three illustrative cases. Pain Med 2010;11:977-980

54. FPM revised curriculum (need website link)

55. Gordon A, Cone EJ, DePriest AZ, Axford-Gatley RA, Passik SD. Prescribing opioids for chronic noncancer pain in primary care: risk assessment. Postgrad Med. 2014 Sep;126(5):159-166

56. Nicholas MK, Molloy AR, Brooker C. Using opioids with persisting noncancer pain: a biopsychosocial perspective. Clinical Journal of Pain. 2006;22(2):137-46

57. Machado GC, Maher CG, Ferreira PH, Pinheiro MB, Lin CC, Day RO, McLachlan AJ, Ferreira ML. Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. thebmj BMJ 2015;350:h1225 doi: 10.1136/bmj.h1225

58. Roelofs PD, Deyo RA, Koes BW, Scholten RJ, van Tulder MW. Non-steroidal anti-inflammatory drugs for low back pain. Cochrane database of systematic reviews 2008 Issue 1. Art No.:CD000396. DOI:10.1002/14651858.CD000396.pub3

59. Franklin GM, Rahman EA, Turner JA, Daniell WE, Fulton-Kehoe D. Opioid Use for Chronic Low Back Pain:A prospective, population-based study among injured workers in Washington State, 2002-2005. Clin J Pain 2009;25:743–751

60. Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, Blow FC. Association between opioid prescribing patterns and opioid overdose related deaths. JAMA 2011;305:1315–1321

61. Franklin GM. Opioids for chronic noncancer pain: a position paper of the American Academy of Neurology. Neurology 2014;83;1277-1284

FURTHER READING

- Ballantyne JC, Shin NS. Efficacy of opioids for chronic pain: A review of the evidence. Clin J Pain 2008; 24:469-478.
- Ballantyne JC, LaForge KS. Opioid dependence and addiction during opioid treatment of chronic pain. Pain 2007;129:235-255.
- Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009; 10:113-130.
- Chou R, Fanciullo GJ, Fine PG, et al. Opioids for chronic non-cancer pain: Prediction and identification of aberrant drug-related behaviors: a review of the evidence for an American Pain Society and American Academy of Pain Medicine Clinical Practice Guideline. J Pain 2009;10:131-146.
- Cohen ML, Wodak AD. The judicious use of opioids in managing chronic noncancer pain. Medicine Today 2010, 11(2) (February):10-18
- Cohen ML, Wodak AD. Opioid prescribing in general practice: a proposed approach. Medicine Today 13:24-32, 2012.
- Finnerup NB, Attal N, Harantoumi S et al. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. The Lancet Neurology 2015; 14:162-173
- Goucke R, Schutze M. What a pain! Managing it through the continuum. Medicine Today 2009; 10(7) (July): 51-60.
- Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: A rational approach to the treatment of chronic pain. Pain Med 2005;6:107-112.
- Hunter New England NSW Health. Reconsidering opioid therapy. May 2014 http://www.hnehealth.nsw.gov.au/pain/health_professionals/medical_practice_guidelines
- Passik SD, Kirsch KL. The interface between pain and drug abuse and the evolution of strategies to optimize pain management while minimizing drug abuse. Exp Clin Psychopharm 2008; 16:400-404.
- The Royal Australasian College of Physicians. Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use. RACP 2009. http://www.racp.edu.au/page/policy-and-advocacy/public-health-and-social-policy

FACULTY OF PAIN MEDICINE PROFESSIONAL DOCUMENTS

POLICY – defined as 'a course of action adopted and pursued by the Faculty. These are matters coming within the authority and control of the Faculty.

RECOMMENDATIONS – defined as 'advisable courses of action'.

GUIDELINES – defined as 'a document offering advice'. These may be clinical (in which case they will eventually be evidence-based), or non-clinical.

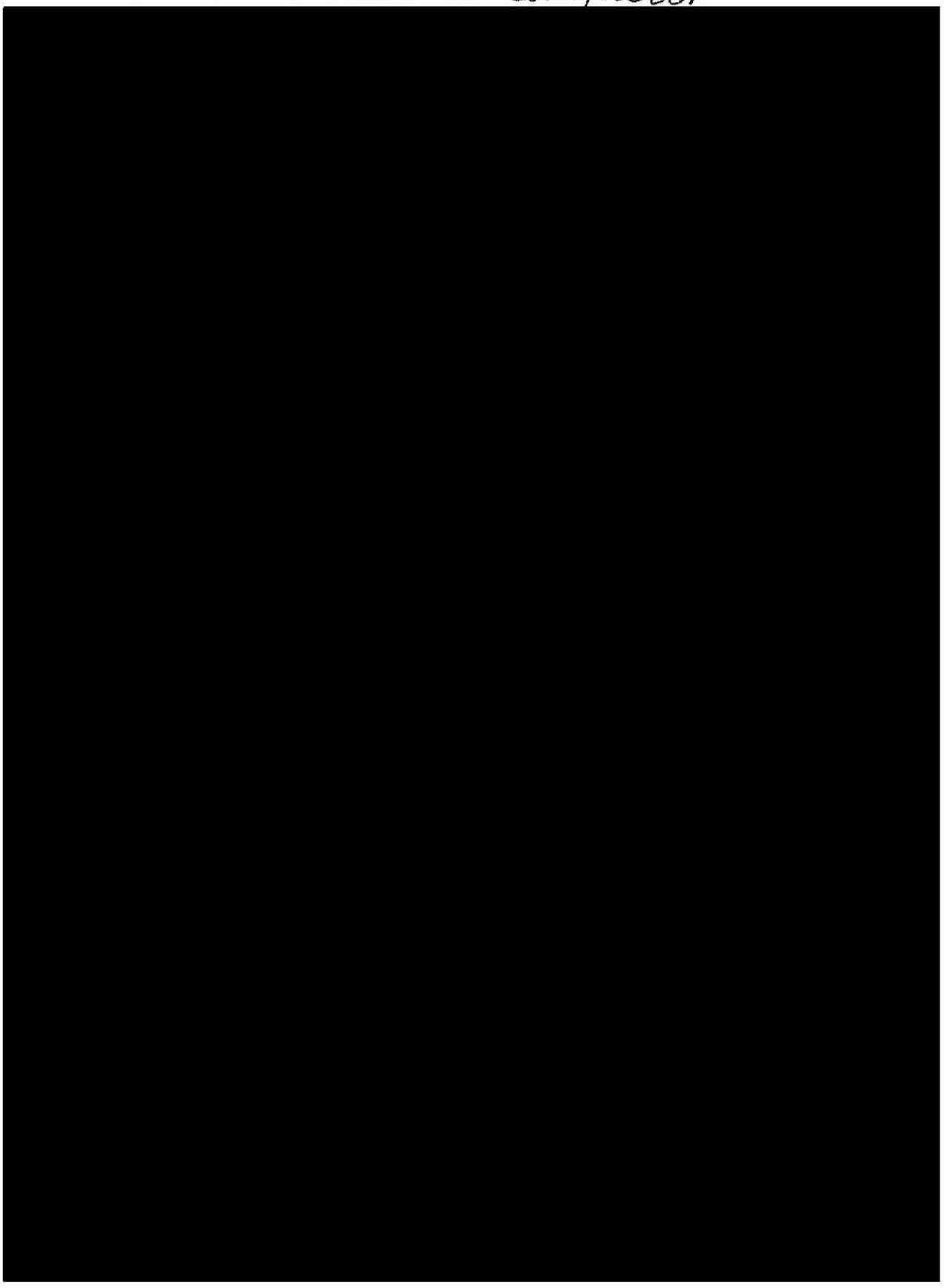
STATEMENTS – defined as 'a communication setting out information'.

I agree with the proposed amendment surrounding Cannabis and cannabinoids, however I feel it does not go far enough.

The Therapeutic Goods Administration needs to show some genuine leadership and go further in its proposed changes to Cannabis and cannabinoids scheduling. To claim that only cannabis produced for human therapeutic use should be classified as a Schedule 8, and all other cannabis remains a prohibited substance is ridiculous. Cannabis is not a highly complex combination of various chemicals. Its a plant which occurs naturally. At minimum the exception for cannabis remaining as a schedule 9 should be removed. The Therapeutic Goods Administration should represent the honest science behind cannabis, that being it is not harmful when consumed by adults, through medical or vaporized methods.

It angers me that the Therapeutic Goods Administration has given credence to the ridiculous restrictions on this substance for so long. I am tired of watching people I care about not have access to the medicine they need. Cannabis has been heavily researched around the world, and its medicinal value for a wide range of health issues is well proven. [redacted] access to medicinal cannabis in more advanced areas around the world. However when [redacted] I have to watch as [redacted] suffer from flares which could be mitigated, and not be able to manage the pain as they have been able too in the past.

Sorry this submission is hand written but we don't have a computer



Thank you for giving us the opportunity to respond to the Advisory Committee on Medicare Scheduling

[redacted]

[redacted]

- We do NOT support the ammendments because we believe no HERB should need to come under such scheduling especially when used for personal use. Herbs grown commercially need to come under some food safety standard and cannabis (and comfrey) could possibly be scheduled under 2-Pharmacy Medicine as they are part of [redacted] Pharmacy or under section 5-caution.
- There is world wide self-evidence to show the healing properties of cannabis and it seems there has never been any recorded deaths from cannabis. There is no justifable reason to schedule cannabis as a prohibited substance. It is unjust to have the growing, proccessing and supply cannabis deemed illegal. It seems to us that this control over medications is being dictated purely by big cooperate pharmeucutical companies thus denying us civil rights of having freedom of choice of our own health matters and health management.
- A plant or any associated botanical material can NOT be illegal (It has never done anything bad or harmful or broken any law). All plants were created for some benifical purpose [redacted]

Therefore Hippocrates sure got it right when he said, 'Let

your food be your medicine and your medicine be your food."

- What can and should be deemed illegal is people misusing and abusing plant derived products in such a way that harm is caused to society as a result of irresponsible actions eg the over consumption of alcohol. Leading to anti-social, detrimental behaviour. Grapes, rye, hops are three of the most common plants used to produce alcohol. but they are not scheduled as being problematic in any way.
- ∴ To schedule cannabis (and comfrey) is discrimination - discriminate against a plant that in turn discriminates against vunerable, sick desperate people who only want the right to health, healing and hope.
- We do not understand how a plant such as cannabis can be singled out as being so harmful that it is declared a prohibited substance when common household item such as nutmeg is deemed a safe plant and food product but if misused can be harmful

  Nutmeg - large amounts can cause renal toxicity, transient psychosis, hallucinations and even death. The dose needed to produce hallucinogenic effects is dangerously close to the toxic dose.

  NB The are many other plants and botanically dervived materials that can have harmful side-effects if misused and abused.

  It all comes down to people being educated and taking responsibity, then all plants and botanical materials will be used for the good [redacted] created them for and the upholding of free choice!

Suggestions (what we believe is just, justifable, protective while maintaining freedom of choice and upholding civil liberty/rights).

- All Australians should have the right to grow and/or access cannabis and cannabis products in the same way they can any other medicinal plants. That should include: (a) the exchanging/giving of the herb to family/friends

  (b) being able to purchase cannabis products such as oil and tinctures at affordable prices at health shops and pharmacies in exactly the same way other medicinal herbs are available in such places. This includes a pharmacist/herbalist being able to make up prescriptions suitable for individual needs.

as different illnesses need different varieties for maximum effectiveness.

(c) the right to obtain the varieties of cannabis and cannabis products best suited to the need and nature of illness eg our son need varieties with high CBD and a mixture of varieties but some people need varieties higher in THC in order to receive the best health results ie for chronic pain etc.

(d) the form in which cannabis is taken for medicinal purposes should be individual choice (oil, tincture, smoking, eating raw product - leaves, seeds) just as a patient has choices of other forms of medications. But at all times the person must take responsibility for using the product safely [redacted]

(e) anyone selling cannabis and cannabis products should registered in some way so ensure safe, responsible practises are upheld and ensure produce is of good, consistant quality. This should be in line with legislation for any other medicinal products.

(f) for people like ourselves who grow, process and supply a family member with cannabis we should be allowed to grow the amount and varieties that adequatly supplies our needs without any restrictions being imposed [redacted] other medicinal herbs), [redacted] to grow commercially [redacted] would need to resigster and come under standards for quality and quanity. It all comes back to personal responsibility and liability.

(g) have the right to teach others how to grow and process cannabis and cannabis produces and educate people on responsible use of the herb as cannabis, like many other plants needs to be used with caution and respect. (We must use all plants sensibly and respectfully for even lettuce can produce intoxication in the form of intense sleepiness – Beatrix Potter's bunnies in Mr Macgreggor's garden for example).

(f) Anyone processing cannabis (oil / tinctures etc) commercially must be registered to ensure quality etc.

In conclusion:

(1) Cannabis and any plant/plant product can never be compared to synthetically produced pharmaceutical products. Man made synthetic products must come under strict regulations and scheduling. Plants and natural products have already passed [redacted] scrutiny. and been fully approved!

(2) Australia has many experts on cannabis - people who know and use the herb. These people can come forward with their knowledge and skills as soon as cannabis is decrimalised. While cannabis is a prohibited substance such people cannot come forward openly. Open the doors! Australians and our Nation will benefit health wise and economically as soon as cannabis is decriminalised and given its rightful status as a self evident medicinal plant. Millions of people have known this for hundreds of years and respect and greatly appreciate this plant that can give health, healing and hope!

* Face the challenge! Make the change! Give us all the right to simply exercise choice. It is simply about the right to live a fulfilling, healthy and happy life. It is about morality, not legality!

[redacted]

[redacted]

18 February 2016

Advisory Committee on Medicines Scheduling (ACMS) *and*
Advisory Committee on Chemicals Scheduling (ACCS)
Therapeutics Goods Administration
Australian Government Dept of Health

Dear Committee Members,

RE: Proposed amendments to the Poisons Standard - ACMS and ACCS meeting, March 2016

I write in strong support of the proposed amendments to the Poisons Standard, that will enable cannabis-based medicine to be rescheduled as an S8 medicine, when being used for a therapeutic purpose and approved through an appropriate governance process. You will be aware of significant interest, and a current research program being supported by NSW Health, in the use of cannabis-based medicine for cancer patients suffering toxicity from chemotherapy and terminal symptoms.

[redacted]

Without the proposed amendments to the Poison standard, the administrative processes & paperwork required to use [redacted] planned cannabis-based medicine both in the hospital environment and at home will be astronomical, given the almost impossible dosing and handling requirements for S9 drugs. This will have a significant detrimental effect on the feasibility of our trial, leading to reduced likelihood of generating high-quality evidence about the efficacy of cannabis-based medicine, a poor investment by NSW Health, reduced likelihood of availability of the drug in a regulated clinical environment if proven efficacious, and community disappointment. I have no doubt that similar impacts will occur for related trials and indications.

Yours sincerely

[redacted]

[redacted]

[redacted] RESPONSE TO TGA PROPOSAL TO RESCHEDULE CANNABIS AT S8

18th February 2016

TGA proposed rescheduling changes

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.

[redacted] **Response**

In principle the [redacted] will support any legitimate rescheduling that allows greater public access to Medical Cannabis. However, after a great deal of research and consideration, the [redacted] has concerns about whether the TGA's proposed rescheduling will achieve that goal.

[redacted] **concerns are as follows**

- Development at S8 will be restrictive and costly. Medical Cannabis can be grown and prepared at low cost. The requirements of pharmaceutical development are costly and will result in extensive long term extra costs to patients, in compensation for this.

- An S8 classification undermines the herbal nature of Medical Cannabis and the relatively straightforward production practices, which could be utilised.

- It appears political alignment to suit the latest Federal developments and Medical Cannabis Bill is influencing the proposed rescheduling which is based more on political and pharmaceutical control of a natural herbal product rather than a legitimate rating based on the plants true medical capabilities.

- An objective, impartial assessment of the Cannabis Plant used medically, based on overseas implementation and policies, would see Medical Cannabis more suitably listed under the Complimentary Medicines category. Any extracts or processed material listed under the ‘Complimentary Medicines Registered’ could include Genus Cannabis with Sativa, Indica and Ruderalis under the plants listing.

- There has been no real attempt to delist THC from the poisons list based on toxicity testing. Other S8 listed drugs such as opiates are harmful even in small doses, however Cannabis has been assessed by other countries as having no history of related death or harmful toxicity.

- The THC Molecule is often misrepresented as 'Psychotropic' and interpreted as Hallucinogenic when its psychoactive effect is essentially a Euphoriant. It is rare for people to hallucinate on cannabis and when used medicinally the benefits of the herbally prepared medications are well documented from individual use here in Australia and on a broader scale overseas.

- An S8 listing could potentially be catastrophic for current patients who will not be able to source their medical whole plant preparations, open source strains and raw plant materials, or a wide variety of mixes.

- An S8 listing would also restrict doctors from gaining knowledge and experience in relation to supporting their patients' use of Medical Cannabis as part of their medical treatment plan.

- The THC molecule is integral to effective cannabis treatments for Cancer, Chronic pain and a range of other disorders. It is analogous at the molecular level to Anandamide, which occurs naturally in the body. The cannabis plant itself doesn't contain THC but instead it contains THC-A. THC only occurs when cannabis is heated; further, at appropriate levels of use is not harmful at all, but therapeutically beneficial.

- A destabilising myth has emerged that the CBD not THC is the effective component of the cannabis plant for medical purposes. In many cases people are being promised Medical Cannabis treatments that 'wont affect them psychoactively'. Most people who have worked with Medical Cannabis for many years and with many patients, know it is the combination treatments that work, utilising differing mixes and various methods of absorption.

- It is obvious the TGA is in a position to protect pharmaceutical interests and an S8 listing will do that, rather than addressing Medical Cannabis use in Australia as a developing whole plant health treatment.

Given these 'listed concerns, it is impossible for [redacted] to fully support the TGA's proposed changes.

[redacted] proposes a broad scale assessment of the current Medical Cannabis situation in Australia, meta-analysis of Medical Cannabis developments including research and legislation worldwide, many of which are herbal based and patient focused. The implementation of 'appropriate' Australian specific guidelines that meet the needs of patients, naturopaths, doctors and specialists who are requesting and advocating for more effective and less toxic medical treatments.

Many patients currently using Medical Cannabis are experiencing great benefits but the vagaries of inconsistent quality and supply is an issue which needs to be addressed. The use of Medical Cannabis needs to be legitimised and quality assured in the best interest of patients. [redacted] agrees entirely with legislative changes, which facilitate this.

The TGA has not carried out feasibility studies in Australia, no statistical analysis of projected usage for identified medical conditions have been completed, no data collection relevant to the therapeutic needs of patients and their conditions, no overall assessment of the therapeutic benefits of Medical Cannabis and no structured plan of feasible implementation have been undertaken.

While it is obvious that the TGA will go ahead with their proposed rescheduling regardless of current worldwide research and models of dispensing, and regardless of the concerns of the Australian community, [redacted] calls for a full-scale public inquiry and independent assessment of the current Medical Cannabis usage and needs. The notion of an 'appropriate' system of Medical Cannabis production and delivery is one that meets identified needs and the current proposal fails to recognise this.

[redacted] support a US style open market herbal based Medical Cannabis system. This model provides for the broadest range of options, products, business development opportunities and usage. The US model, which allows for some individual state based control has been successful for over 20 years. This model factors in personal grow rights, herbal production, medical research and corporate development. Many thousands of businesses are producing a variety of Medical Cannabis products to meet individual patient needs.

If Australia engages in a misguided, restrictive Pharmacy only based approach, with tightly controlled production, the black-market production and illegal growing and self production currently occurring in Australia will dwarf any TGA approved delivery by hundreds of tonnes and; expose legitimate Medical Cannabis users to the risk of contamination of inferior products without the instigation of a practical and legitimate framework to regulate herbal dispensing. If patients are offered no choice but the use of pharmaceutically produced sub grade 'standardised' Medical Cannabis, split molecule treatments, low strength preparations, as being proposed by the TGA, and practitioners are not educated in the true benefits of cannabis as a medicine, people will be sold a TGA approved treatments of limited therapeutic effect, putting their lives at risk.

[redacted] recommends the TGA consider our concerns, recognising our knowledge and experience in this matter and reconsider the proposed rescheduling changes in favour of a more appropriate best practice Australian model of herbal dispensing and patient focused delivery.

[redacted]

[redacted]

16 February 2016

Advisory Committee on Medicines Scheduling

Therapeutic Goods Administration

PO Box 100,

Woden, ACT 2606

medicines.scheduling@tga.gov.au

Re: Proposed amendments to the Poisons Standard – ACMS and ACCS meeting March 2016 Consultation

Dear Sir/Madam,

Thank you for the opportunity to respond to the TGA's proposed amendments to the Poisons Standard.

[redacted]

[redacted]

Executive summary

1. We fully support the amendment to create new Schedule 8 entries for:
    a. Cannabis (plant and flowering tops);
    b. Botanically derived extracts (or derivatives) of cannabis; and
    c. Tetrahydrocannabinols (THC) where they are botanically derived from cannabis.
2. We support only restricting access to these substances via a uniform National scheme where possible, such as:
    a. clinical trials conducted under the TG Act (ie clinical trial notification or clinical trial exemption); and
    b. the Special Access Scheme and Authorised Prescriber Scheme

    We do not support the establishment of different state access regimes that may result in adverse patient behaviour and an unnecessary additional layer of authorisation.

1. New Schedule 8 entries

We support the inclusion of cannabis (plant and flowering tops) and botanically derived extracts (or derivatives) of cannabis in Schedule 8 for the following reasons:

a. These products can be cultivated and manufactured in manner that ensures a consistent high quality medical product;
b. The suite of chemical compounds in the cannabis plant may have a greater therapeutic advantage that any principal ingredient alone; and
c. Potentially greater affordability for patients.

International clinical studies and the use of dried, as well as whole plant derived extracts, in other jurisdictions such as Canada and the Netherlands, have shown that these products are an important inclusion in the range of products that a medical practitioner may consider in treating their patients.

These products can be clonally cultivated and manufactured in accordance with Good Manufacturing Practices as shown in Canada and the Netherlands where consistent high

quality herbal product is produced. The Dutch licensed grower Bedrocan, and the 27 producers licensed under Health Canada's Marihuana for Medical Purposes Regulations regime provide examples of producing medical products under these type of processes.

Cannabis, and its whole plant derived extracts, contain over 80 different phytocannabinoids along with many other molecules such as terpenes and flavonoids. These phytocannabinoids mimic endocannabinoids by binding to the cannabinoid receptors in the body. This interaction allows for the majority of cannabis' therapeutic benefits. The body releases other chemicals at the same time as endocannabinoids, creating a stronger effect than that achieved with endocannabinoids alone. Many researchers think there is an equivalent entourage effect for phytocannabinoids. Studies have indicated that the synergy between the various cannabinoids and terpenes in cannabis produces a greater effect than any single cannabinoid on its own.[1]

Although clinical efficacy of a product is of primary importance, affordability is also an important factor for Australian patient access. The more refined the product the greater the cost. Extracting out single cannabinoids and formulating, or manufacturing synthetic cannabinoids, is a more extensive process that the production of whole plant extracts. Studies have shown the importance of affordability in instances where cannabinoid medicines may be used as a substitute, or to supplement and reduce the use of, subsidised opitate prescription medications. Patients in the USA and Canada are using cannabis as a substitute for opiates analgesics due to fewer side effects, better symptom management, lower risk of dependence and no possibility of fatal overdose. The major barrier to substitution however was found to be affordability.[2]

2. Additional controls on access

We submit that a Commonwealth scheme where possible, be implemented and would suggest that the following existing TGA schemes for unapproved products are appropriate:

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[1] Owens B. Drug development: The treasure chest. Nature 525, S6–S8, 23 September 2015 http://www.nature.com/nature/journal/v525/n7570_supp/full/525S6a.html
Russo EB. Taming THC: potential cannabis synergy and phytocannabinoid – terpenoid entourage effects. British Journal of Pharmacology 163(7): 1344-1364, 2011.

[2] P

a. clinical trials conducted under the TG Act (ie clinical trial notification or clinical trial exemption); and
b. the Special Access Scheme and Authorised Prescriber Scheme

Given the majority of cannabinoid medications will not be on the Australian Register of Therapeutic Goods (**ARTG**) these access schemes will already need to be employed by patients and prescribers.

The reasons why many cannabinoids medicines will not be on the ARTG are varied. The key reason being the difficulty in gaining patent protection in relation to cannabis-derived products. The economics of registration are such that companies need some patent protection to recoup costs over a period of time. Additionally the relatively small pharmaceuticals market in Australia is another factor on why companies are unlikely to invest significantly in getting new cannabinoid medications listed through the TGA.

The established TGA schemes for unapproved products, such as the Authorised Prescribers Scheme, provides the necessary checks and balances to ensure patient safety and utilises appropriate decision makers, namely:

a. the prescribing medical practitioner – no-one is more appropriate for determining what is best for their individual patients and the disease or symptom to be treated;
b. relevant ethics committees or specialist colleges, to assess the safety of the product and the suitability of the medical practitioner to prescribe; and
c. an impartial third party, ie the TGA, to assess the hierarchy of evidence in respect to the efficacy and safety of the product, the patient's condition and the requesting medical practitioner's qualifications.

It is essential that evidence can be provided in respect to the efficacy and safety of any unapproved cannabinoid medicines and logical reasoning on why these medicines should be used.

Given the nature of these medicines, there are however some qualifications in the implementation of the established TGA schemes.

The identification of 'product' will need to be clarified to be a cannabinoid medicine of a *particular* chemical composition. Whether it is dried herbal product or a botanically

derived extract there must be a form of standardisation that ensures a claim of efficacy made for a particular product, or reference to a product approved overseas, is of the same chemical composition. As noted previously, cannabis, and its whole plant derived products, may include over 80 different cannabinoids. These cannabinoids may have different effects on the human endocannabinoid system and these therapeutic effects can vary based upon the ratio of these cannabinoids in the product. Arguably other chemicals contained in the cannabis plant, such as terpenes, may also play a therapeutic role.[3] Canadian producers include the content of two main cannabinoids delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) on the labelling their cannabinoid medicines. Bedrocan Netherlands provides details of the content of three cannabinoids THC, CBD, and Cannabinol (CBN). To fully identify a 'product' a greater analysis of the chemical composition of the cannabinoid medicine may be required.

Any product that is produced in Australia that is to be assessed under the Authorised Prescribers Scheme or Special Access Scheme, should have analytical evidence that it is of the same chemical composition to a product used in clinical studies, or is approved for use overseas, if these criteria are to be provided as supporting evidence for authorisation.

Additionally, consideration by the TGA of other approved products that include the same active ingredients in the same therapeutic class should include comparison of the suite of chemicals contained and not just the cannabinoids THC and CBD. For example, a whole plant extract from a particular cannabis strain may perform very differently to an approved product, such as the plant extract [redacted], even though both may contain an equal ratio of THC and CBD. This should not rule out the use of that particular whole plant extract if evidence can be provided on why use of that particular extract product may be preferable to the approved product.

Individual state authorisation

We submit that an additional layer of state/territory based authorisation to the existing TGA access schemes for unapproved products is not required for the protection of Australian patients.

[3] Russo EB. Taming THC: potential cannabis synergy and phytocannabinoid – terpenoid entourage effects. British Journal of Pharmacology 163(7): 1344-1364, 2011.

In the United States, there is legal inconsistency between state laws in respect to the ability of patients to access cannabinoid medicines.

Research has been undertaken into the effects of the United States' variability in regulatory frameworks in the 23 states that permit medical cannabis use, on patient behaviour.[4] It was shown that discrepancies in pricing and availability of medicines resulted in patients crossing borders to access medicines.

Ideally there should be only one Commonwealth access scheme so that there is consistency across all states and territories.

Thank you once again for this opportunity to comment.

Yours sincerely

[redacted]

[4] Executive Summary, The State of the Legal Marijuana Markets, 4th ed, ArcView Market Research and New Frontier, February 2016.

[redacted]

Committee Secretary

Advisory Committee on Medicines Scheduling

PROPOSED AMENDMENTS TO THE POISINS STANDAD: Cannabis and cannabinoids

[redacted]

Background

The severity and frequency of seizure activity varies widely in people living with epilepsy. Approximately sixty five to seventy percent of people diagnosed with epilepsy have their seizures well controlled on the first or second anti-epileptic medication they try. The remaining thirty to thirty five percent, unfortunately, continue to experience seizure activity despite trying numerous combinations of currently available anti epileptic medications. They are considered to have intractable or medication resistant epilepsy. Of this group, some are diagnosed with catastrophic types of epilepsy, where they suffer recurrent severe and damaging seizures on a daily basis. This is a devastating fact of life for many families in Australia where tragically death, before the child reaches adulthood, could be the outcome.

However new hope has been given to these families from the positive results of early research and clinical case studies of potential treatment options that can significantly reduce the severity and frequency of seizures. These treatments are derivatives of the cannabis plant.

[redacted] understands the legal issues in Australia: that cannabis cultivation and use is not legal in any Australian jurisdictions for any purpose, even though the international drug treaties to which we are party permit the medical and scientific use of drugs whose recreational use is prohibited.

We understand from social media and other sources that a number of consumers (parents) in Australia are gaining access to cannabis derivatives to treat seizures in the form of tinctures and oils. Given the catastrophic and debilitating nature of their children's epilepsy conditions it is not difficult to understand their desperation. These parents report immense improvement in the severity and frequency of their children's seizures and overall quality of life. Concern has been expressed that these consumers are using home-grown and black market cannabis of uncertain medicinal quality, and that these desperate parents are also breaking Australian laws.

[redacted] supports any activity that expedites the provision of access to a legal source of cannabis based products for research and medicinal use whilst protecting individuals involved in the cultivation, manufacture, distribution, prescription, supply and administration of these product from prosecution and threat by government authorities to remove children from the care of their families.

[redacted]

[redacted]

Focus of this submission

In essence [redacted] supports

- the down-regulation of Cannabis for medicinal purposes and it's derivates out of a Schedule 9 category
- Schedule 8 category for: Cannabis plant and flowering tops with high tetrahydrocannabinols (THC) and low cannabinol (CBD) ratios; synthetic THC; and pure botanical extracts of THC
- Schedule 4 category for: Cannabis plant and flowering tops with low THC / high CBD; synthetic cannabinoids; pure botanical extracts of cannabinoids; and THCa the non psychotropic form of THC.
- That access to bespoke compounded botanical cannabis products are not blocked nor delayed by the TGA due to a lack of listing within a particular schedule as scientific advances are made in the future, that this issue is addressed whilst considering the rescheduling of cannabis and its derivatives.

Summary

[redacted] strongly supports the proposed rescheduling of cannabis and its derivatives offering hope to hundreds of families living with the everyday reality of intractable and catastrophic epilepsies. For many of our families time is of the essence, with children failing to progress or regression of their cognitive function and skills the longer they wait to legally access medicinal cannabis products to manage their child's seizures.

We welcome the establishment of a national framework for the regulation of medicinal cannabis and look forward to contributing to the ongoing development of the underlying policies, procedures and educational materials relevant to our consumer base.

Yours Sincerely

[redacted]

[redacted]

18 February 2016

By Email: medicines.scheduling@tga.gov.au

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

Dear Sir/Madam

Proposed amendments to the Poisons Standard

[redacted]

[redacted] in relation to the proposal (**Proposal**) set out in the "Proposed amendments to the Poisons Standard – ACMS and ACCS meeting, March 2016" to create new entries in Schedule 8 of the *Poisons Standard* (**SUSMP**) for cannabis and botanically-derived extracts (or derivatives) of cannabis, including tetrahydrocannabinol (**THC**).

The Proposal stipulates that, unless they have been imported pursuant to the *Customs (Prohibited Imports) Regulations 1956* (Cth) (**CPIR**), the specified substances should be produced or manufactured in accordance with the *Narcotics Drugs Act 1967* (**NDA**) and, in this regard, contemplates the amendment of the NDA by the passing of the *Narcotics Drugs Amendment Bill 2016* (Cth) (**ND Bill**),[1] which provides for a national scheme for the cultivation of medicinal cannabis and the production of medicinal cannabis products.

[1] TGA, 'Cannabis re-scheduling proposal – questions and answers', 21 January 2016 <https://www.tga.gov.au/behind-news/cannabis-re-scheduling-proposal-questions-and-answers> (Last accessed 16 February 2016)

[redacted]

[redacted]

Accordingly, [redacted] an interested party in the Proposal and, on this basis, would appreciate the opportunity to participate in any further dialogue regarding the specific scheduling options or the implementation of the regulatory framework that will underpin the legislative changes.

In relation to the Proposal specifically, [redacted] makes the following submissions for consideration by the medicines delegate (**Delegate**).

Submissions in response to the Proposal

[redacted] notes that if the ND Bill is passed substantially in its current form, new entries in the SUSMP for cannabis, and botanically-derived extracts or derivatives (including THC) of cannabis, will be required to enable the supply of medicinal cannabis products pursuant to licences issued under the NDA. [redacted] also understands that the Proposal to include these substances in Schedule 8 is on the basis that some of the substances present in cannabis (such as THC) possess psychotropic properties.

However, although [redacted] accepts that access to cannabis and its botanically-derived extracts should not be unfettered, it is [redacted] view that the scheduling of these substances ought not be subject to unnecessary restrictions on supply.

With this in mind, if the substances are to be listed in Appendix D of the SUSMP and subject to additional restrictions on supply, [redacted] considers that it would be appropriate to list the substances in Item 1 of Appendix D, such that they are "*available only from or on the prescription or order of an authorised medical practitioner*". This accords with the first option in the Proposal and is consistent with the current listing of nabiximols in Item 1 of Appendix D.

In relation to determining whether or not other restrictions ought to apply to the supply of products derived from cannabis, [redacted] submits that the various access schemes permitted under the *Therapeutic Goods Act 1989* (Cth) (**Act**) and the *Therapeutic Goods Regulations 1990* (Cth) (**Regulations**) will sufficiently restrict the supply of medicines to those that are either registered in the Australian Register of Therapeutic Goods, or are supplied through one of the alternative access schemes provided for under sections 18 and 19 of the Act, and regulation 12 and Schedule 5 and 5A of the Regulations.

Further to the above, [redacted] believes that option three, which proposes the creation of a special entry in Appendix D of the SUSMP for "*Poisons available only from or on the order of a specialist physician*", would be unduly restrictive. In particular, given that medicinal cannabis has a range of therapeutic uses for a number of serious medical conditions, it would not be appropriate to restrict the use of medicinal cannabis products to particular types of "specialist physicians".

[redacted]

[redacted]

Conclusion

[redacted] welcomes the Proposal as a means of facilitating the supply of medicinal cannabis products in conjunction with the national regulatory scheme contemplated by the ND Bill.

However, in considering the options outlined in the Proposal to restrict the supply of medicinal cannabis products, [redacted] urges the Delegate to be mindful that the scheduling of cannabis and its botanically-derived extracts and derivatives (including THC) should not impose unnecessary restrictions on access to those substances.

Please do not hesitate to contact the undersigned if you have any questions regarding the above.

Yours sincerely

[redacted]

[redacted]

SUBMISSION TO THERAPEUTIC GOODS ADMINISTRATION CONSULTATION ON AMENDMENTS TO THE POISONS STANDARD

FEBRUARY 2016

[redacted]

The Australian Government has expressed concern about Australia's increasing healthcare burden. This financial burden will increase significantly with inevitable population growth. [redacted] is also aware that in Australia like in most developed nations addiction to pharmaceutical drugs is a common and increasing problem.

There is also increasing public understanding that in the past pharmaceuticals have been approved and released into the public arena without sufficient knowledge about the long term impacts of those pharmaceuticals and without an understanding of the impacts of the drugs in combination with other pharmaceuticals. This has led to major problems in most developed countries related to high levels of poly-drug addition.

Cannabis is an ancient medicinal plant, revered in many cultures for its therapeutic benefits and highly regarded by those doctors who are familiar with its uses because of its relative safety as a medication. Unlike very many of the pharmaceutical drugs that are currently approved for administration, there is no history of death from cannabis medications. That is not the case for synthetic cannabis.

Therefore [redacted] supports the rescheduling of Cannabis from Schedule 9 to Schedule 8 and the development of an ethical regulated medicinal Cannabis

Hydrangea

Hydrangea paniculata grandiflora

https //i.ytimg.com/vi/5kirPul7kTQ/maxresdefault.jpg

Readily available as a garden flower and in nurseries

Smoking can result in euphoria, confusion, sedation, etc - contains a dangerous chemical in the cyanide family.

Lettuce

Lactuca

Readily available in supermarkets and in vegetable gardens

Varying amounts (depending on cultivar) of 'lettuce opium' – lactucarin. Mild sedative and eases pain.

Nutmeg

Myristica fragrans

Readily available in supermarkets and most home kitchens

Mind altering and hallucinogenic effects – dangerous toxicity and overdosing requiring hospitalisation reported.

Scotch Broom

Cytisus scoparius

http://www.shim.bc.ca/invasivespecies/images/Broom_control.jpg

Weed of national significance – widespread throughout south-eastern Australia

Able to cause stupor, euphoria, stimulation and excitation – can have dangerous effects on the heart.

Amanita Mushroom

amanita muscaria

Widespread throughout south-eastern Australia, generally found under pine trees.

Euphoria, sedation, delirium, psychedelic - poisonous, can cause seizures.

Cannabis

Cannabis sativa, indica, ruderalis

Illegal – currently schedule 9 (prohibited).

Why?

Should be readily available for medicinal use.

Can cause a feeling of wellbeing, relaxation, increased appetite, euphoria, altered conscious perception - has well-known healing properties.

References: *Schifano, Orsolini, Corkery, et al (2015)* Novel Psychoactive Substances of Interest for Psychiatry, *World Psychiatry, Feb 2015*; *M J Superweed, (1970),* Herbal Highs: a guide to natural & legal narcotics, psychedelics & stimulants, *Stone Kingdom Syndicate 1970; Ehrenpreis, DesLauriers, Lank, Armstrong, Leikin (2014),* Nutmeg Poisonings: a retrospective review of 10 years experience from the Illinois Poison Centre, 2001-2011, *J Med Toxicol, June 2014.*; www.drugs-forum.com *(February 2016)*