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.

Representatives from

have all been requested to

appear before the Senate inquiry... investigating corporate tax avoidance... suppliers of publicly subsidised medicines in Australia recorded sales of nearly \$5 billion last year but paid an average of just \$10 million each in company tax.

http://www.smh.com.au/business/comment-and-analysis/big-pharma-bosses-front-up-to-senate-inquiry-into-corporate-tax-avoidance-20150701-gi2u7v.html

The psychological and financial COST of the drug war on medical users would be eliminated. Arrests, loss of licenses, clogged up courts; cost of roadside drug testing - laboratory tests cost around \$800 each; kits \$50 and the estimated increase in road side testing is expected to increase to around 97,000 in the next year.

What other 'medication' is targeted like this by police? The fear of prosecution makes many users interrupt treatment (and relief from symptoms) in case they get "caught" - unlike prescribed medications that carry a warning about "not operating machinery" – but there is NO PENALTY for doing so. It is unfair, unjust and unreasonable and reeks of bias.

Medical users need access without fear of being prosecuted for their choice of health care. They are at the **mercy** of the LAW and discretion of police and currently there is NONE.

Re: "Cannabis and THC would remain Schedule 9 substances....when not for human therapeutic use..."

There is **NO BENNFIT** to this suggested proposal either.

Cannabis taken in any form works on our built-in endo-cannabinoid system which keeps the body in homoeostasis, therefore all use is therapeutic. People use cannabis "recreationally" to "make them feel better" i.e. reduce stress, lift their mood or help induce sleep.

Our body hangs onto cannabis for a long time after "recreational" use, because our body recognises it as a useful substance and this is why it shows up long after use in roadside testing.

If cannabis were removed from the poison schedule altogether there would be HUGE advantages:

- 1. There would be no leakage into illicit market because there will be no "illicit" market
- 2. Tax could be collected on (only) recreational users
- 3. It would be a safer alternative for kids seeking a "high" as opposed to huffing and sniffing cleaning products;
- 4. it would substantially reduce burden on taxpayers for health;
- 5. it would substantially reduce burden on taxpayers for policing the failed drug war cost of man power for roadside testing and court appearances; costs of clogged up courts and free up the courts in criminal justice system enabling a back log of real crimes (with victims) to be addressed; cost of testing laboratory \$800 / kits \$50 x 97,000 anticipated tests in coming year); cost of search and destroy missions every summer.

If cannabis were not a prohibited substance our streets would be a great deal safer,.
 Australians are a pleasure seeking nation - nothing will change that - and cannabis poses much less of a threat than alcohol abuse.

All users are at the mercy and discretion of the LAW which currently shows NONE.

Restricted access to the cannabis is NOT appropriate access. The law is the only thing that keeps it this way. The people will continue to use it regardless of consequences. Removing Cannabis from the poison schedule is a good start to removing its illicit status, and a huge step toward improving the health of a nation.

In conclusion, I would like to add that

will be submitting a Declaration

addressing all countries and their representatives taking part at the UN General Assembly Special Session on Drugs 2016 (UNGASS2016) to adopt it and incorporate it into the Declaration of the UNGASS2016.

The declaration requires that the UNGASS2016 request that Governments either:

exclude cannabis out of the 1961 UN Convention with no other actions,

or

prepare debate and accept a Special UN Convention on Cannabis, that would be based on the scientific evidence, human rights and the well-being of societies;

and

as suggested by the World Health Organisation, re-schedules cannabis to account for its medical use, and in amendment prepare special regulations for medical cannabis that would not mimic those of medical opiates and opium.

This General Assembly Special Session on Drugs 2016 may be the catalyst that begins to change the face of cannabis prohibition for the future. With world wide acceptance snowballing, it may be wise to consider the possible outcomes and repercussions of this session on the Australian people, and take steps now that will prevent double handling of the issue at a later date - costing more time, money and lives.

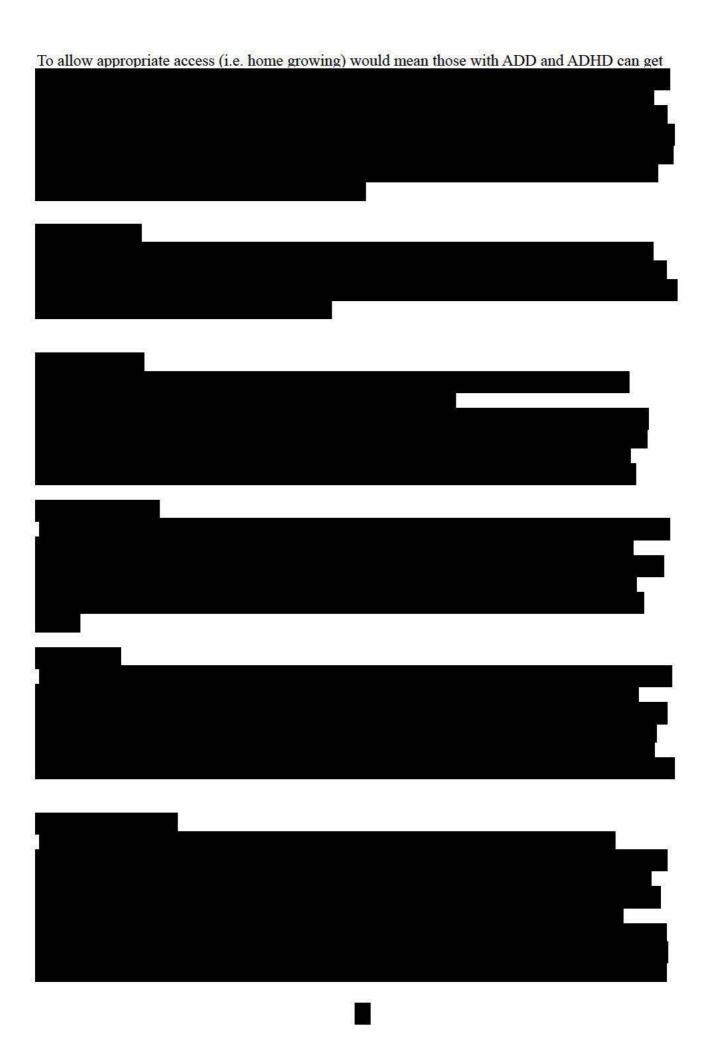
You have to see that change is inevitable. Why not be a leader rather than a follower in this important decision.

Thank you for the opportunity to speak on behalf of over 10,000 known users of medical cannabis

Yours sincerely



As an assessment of how the proposed change will impact on sort feedback about what they see as the likely benefits or costs to them (financial or non-financial). The following is a selection of their comments as MAJOR STAKEHOLDERS:	
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Electronic submissions are preferred and should be emailed to:

•medicines.scheduling@tga.gov.au

AND

 $\hbox{\bf •} chemicals.scheduling@health.gov.au$

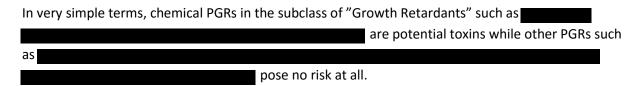
Plant Growth Regulators (PGRs)

This article details a very serious issue in the legalisation of cultivation of cannabis for medicinal use in Australia. While not directly about ideal growing practices, this is a warning about less than ideal growing practices currently used by black market commercial cannabis growers all over Australia, and the world.

While this article cannot source some statements made, this is only due to the current unavailability of research possibilities into the chemical make-up of black market commercially supplied cannabis in Australia.

What is a Plant Growth Regulator (PGR)?

The term 'Plant Growth Regulator' covers a broad range of synthetic and natural (organic) compounds that effect plant growth. Just a few of these pose a risk to consumers while others are non-toxic.



The Problem With PGRs

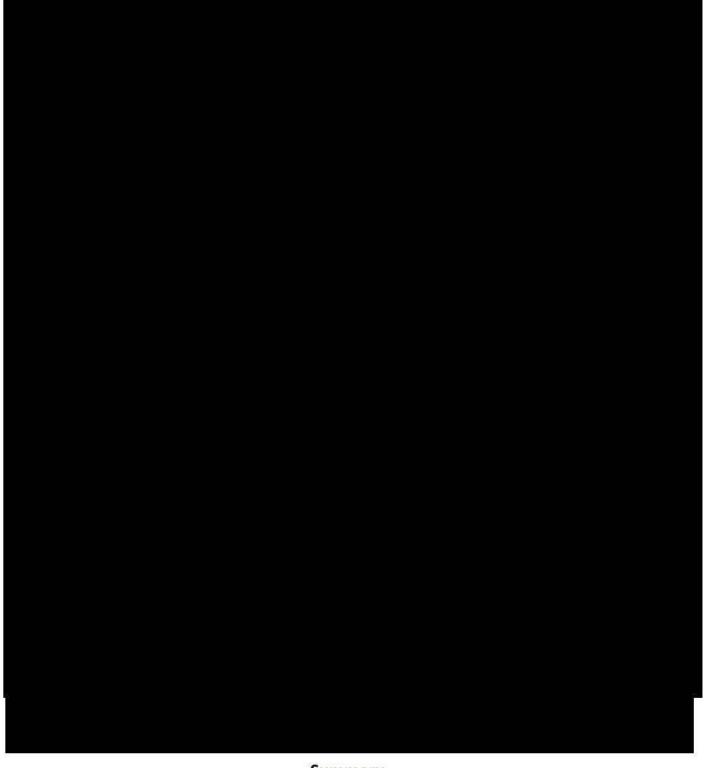
PGR based products halt the upward (apical) growth of a plant, thus giving cannabis growers control over the height of the plant and keeping nodes close and encouraging dense bud-set. This is desired for many indoor growers who wish to grow numbers of shorter plants, or growers who work in areas with limited ceiling height.

Additionally, PGR products can increase yields where cannabis plants are grown in less than ideal conditions. This means inexperienced growers, or growers who fail to optimise their environments, can achieve higher yields when using PGRs. These products are often popular with black market commercial growers. Large scale black market cultivators are responsible for large amounts of commercially available cannabis that consumers are unwittingly purchasing, which may contain these toxic chemicals.

In Australia especially, where PGR flowering additives first became available through hydroponics stores, large numbers of commercial cultivators use these product.

Identifying Chemical "Growth Retardants"

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Summary

The use of PGR chemicals on black market, large scale commercial crops of cannabis in Australia is a huge public health issue, and one which could be solved by regulating and licensing growers within the country. Cannabis is said to be one of, if not the largest, consumable crops in the world. With a black market rampant with possibly toxic PGR's, and no way to test or regulate the supply to the increasingly large medical patient populous, it is imperative that now we focus on creating a regulated supply chain from experienced grower, to carer/provider, to patient (with a sample sent for analysis of Cannabinoids, Terpenes and possible toxins before final packaging).

Consultation on proposed amendments to the Poisons Standard (Cannabis and cannabinoids) – Submission for consideration by the Advisory Committee on Medicines Scheduling in March 2016



Purpose

makes this submission on proposed amendments to the Poisons Standard for cannabis and cannabinoids referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS) in March 2016.

Summary position

- supports the proposal to enable appropriate access to medicinal cannabis products for therapeutic use by creating new Schedule 8 entries for cannabis (plant and flowering tops), botanically derived extracts of cannabis, and tetrahydrocannabinols where they are botanically derived from cannabis.
- supports the use of standardised pharmaceutical products which have been evaluated for safety and efficacy. holds a firm position that smoking of cannabis is harmful and therefore does not support the smoking of cannabis plants and flowering tops as a form or method of administration of medicinal cannabis.
- strongly supports the conduct of clinical trials, exchange of research experience and timely dissemination of outcomes with a view to enhancing our understanding and evidence base of the use of medicinal cannabis in the management of various conditions and symptoms.
- supports the inclusion of additional controls on these substances through an entry in Appendix D of the SUSMP or similar arrangement.
- supports appropriate state and territory regulatory arrangements to authorise prescribers
 and determine patient eligibility. However, we believe that over time and with accumulation of
 evidence, such arrangements should be reviewed, including for national consistency so that
 the location of patients does not determine or impact on access to specific medicinal
 cannabis products.

Background

There has been a growing compassionate view that there should be less of a barrier to the medicinal use of cannabis by individuals who have no other reasonable therapeutic alternative and seek some quality of life. The pharmacy profession supports the National Medicines Policy (NMP) framework which includes as a key objective, timely access to medicines for all Australians.²

Rescheduling proposal

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

² Australian Government Department of Health and Aging. National Medicines Policy. 2000. At: www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policy

• 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".

Cannabis and Cannabinoids

Cannabis is a plant (*Cannabis sativa*) consisting of approximately 500 natural components, of which up to 80 are cannabinoids.³ notes that under the Single Convention on Narcotic Drugs all cultivators of cannabis plants are required to deliver their total crop of cannabis (including

³ National Cannabis Prevention and Information Centre. Cannabinoids. Factsheet 20. Randwick: NCPIC; 2011. At: https://ncpic.org.au/media/1529/cannabinoids.pdf

flowering tops) to the government agency which regulates cannabis production.⁴

Synthetic cannabis reportedly has more serious side effects than botanical cannabis. In 2015 there were two deaths in Queensland linked to the use of synthetic cannabis. supports the rescheduling of botanically derived cannabis but not synthetic cannabis.

Some pharmacists have noted that since cannabidiol is currently in Schedule 4, the proposal to reschedule cannabis to Schedule 8 appeared to be inconsistent. In notes that the effects of cannabidiol are regarded as non-psychoactive and the substance is not reported to possess any significant abuse potential. In view is that a Schedule 4 classification for cannabidiol is appropriate based on its safety profile and this allows for appropriate medical oversight and facilitates the conduct of clinical trials. Further, In believes that in the context of the psychoactive effects, pharmacological profile and broader side effects of cannabis, Schedule 9 and proposed amendments to Schedule 8 for cannabis are appropriate.

Safety and Efficacy

As medicines experts, pharmacists are aware of the short-term and long-term harmful physiological and psychotropic effects of recreational cannabis use. Governments and all health professionals agree on the health risks associated with smoking and seek to discourage smoking of any substance including cannabis. While we understand some patients may accept or prefer to smoke cannabis, does not support this mode of delivery given the uncertain or unknown dosing quantity and other side effects, as well as the risk of harm through ingestion (e.g. passive smoking) by carers, children and the public.

It is a fundamental requirement that medicines in Australia meet acceptable standards of safety, quality and efficacy. Standardisation of composition, formulation, dose form and dosage of medicinal cannabis is required from a public and patient safety perspective. 'Street' cannabis which is not regulated has many safety issues, such as⁷:

- contamination by mould, bacteria, ground glass, fly spray and heavy metals
- unsafe levels of solvent residues and toxic pesticides
- releasing ammonia when heated (including in a vaporiser).

Standardisation of medicinal cannabis will enhance the ability to compare results across different clinical trials allowing the creation of an evidence base for the therapeutic use of cannabis.

⁴ United Nations. Single Convention on Narcotic Drugs, 1961. At: www.unodc.org/pdf/convention_1961_en.pdf

⁵ National Cannabis Prevention and Information Centre. Synthetic cannabinoids. Factsheet 25. Randwick: NCPIC; 2011. At: https://ncpic.org.au/media/1534/fact-sheet-25.pdf

⁶ Victorian Law Reform Commission. Medicinal Cannabis: Report. Melbourne: VLRC; 2015, Aug. p. 176. At: http://lawreform.vic.gov.au/sites/default/files/VLRC_Medicinal_Cannabis_Report_web.pdf

⁷ ibid. pp. 188–9.

Research

notes that current potential uses of cannabis include the following^{8,9}:

- for the relief of severe nausea and vomiting due to chemotherapy
- for the relief of pain associated with cancer or neuropathy
- to stimulate appetite in patients living with HIV/AIDS or cancer
- to ameliorate spasticity due to multiple sclerosis or spinal cord injury
- to reduce the incidence of seizures in treatment-resistant epilepsy in children and young adults.

The lack of rigorous clinical evidence on the benefits of cannabis presents a challenge for governments and health professionals. It is therefore important that clinical trials and research are undertaken to allow analysis and comparisons of outcomes in a timely manner. clinical trials of medicinal cannabis conducted with medical supervision or oversight. The patient and/or carer for participation in these trials must provide informed consent. The use of medicinal cannabis is not without risk and many side effects have been reported including 10,11:

- psychotic effects including precipitating and exacerbating schizophrenia
- mood effects including anxiety depression and paranoia
- impairment of learning, memory and motivation
- dependency
- dry mouth, dental and periodontal disease
- cardiac effects such as tachycardia
- pregnancy complications
- impairment of concentration and psychomotor performance.

PSA supports clinical trials and research which will help to quantify these side effects.

11 National Cannabis Prevention and Information Centre. Cannabis and mental health. Factsheet 3. Randwick: NCPIC; 2012. At:

https://ncpic.org.au/media/1512/cannabis-and-mental-health.pdf

⁸ National Cannabis Prevention and Information Centre. The use of cannabis for medical purposes. Bulletin series 18. Randwick: NCPIC; 2014. At: https://ncpic.org.au/media/1931/the-use-of-cannabis-for-medical-purposes.pdf

⁹ The Epilepsy Society of Australia. Marijuana and its derivatives in the treatment of epilepsy [position statement]. At: www.epilepsy-society.org.au/resources/documents/Marijuanaanditsderivativesinthetreatmentofepilepsy.docx

¹⁰ Victorian Law Reform Commission. Op. cit. pp. 47–8.

The Victorian Law Reform Commission report¹² on medicinal cannabis suggested that access to medicinal cannabis for clinical trials could be achieved in a timely manner if imported products are used, rather than waiting for the establishment of legal cultivation and manufacture in Australia. PSA therefore supports the inclusion of products which have been produced in Australia or imported in accordance with the relevant legislation.

Additional access controls

An entry in Appendix D of the SUSMP to restrict access to medicinal cannabis for use in clinical trials by authorised prescribers would facilitate research into the current potential therapeutic uses. While restriction of access in this manner is supported initially, believes that over time, with experience, analysis of clinical trial results, and increased scientific knowledge and evidence, it would be reasonable to review and tailor or refine the restrictions.

Medicinal cannabis is expected to be used across a range of conditions and patient groups. We note that state and territory regulatory arrangements will influence the designation of authorised prescribers and determination of eligible patients. Where the evidence base for the therapeutic use of cannabis becomes more readily available, would express support for access arrangements to be made as equitable as possible nationally so that patients with certain conditions are not inadvertently denied access based on their location.



17 February 2016

¹² Victorian Law Reform Commission. Op. cit. p. 122.

Therapeutic Goods Administration
cc: Advisory Committee on Medicines Scheduling
Email: medicines.scheduling@tga.gov.au.

RE: Consultation: Proposed Amendments to Cannabis including THC in the Poisons
Standard

To Whom It May Concern:

We, strongly support the amendment of cannabis plant including Tetrahydrocannabinols (THC) from a Schedule 9 (S9) to a Schedule 8 (S8) substance in the Poison Standard when there is an adequate level of control over access.

Rescheduling Cannabis and THC

The decision to include a substance in a particular Schedule takes into account many criteria such as the purpose of use, potential for abuse, safety in use, the need for the substance and toxicity. S8 substances allow for greater accessibility compared to an S9 substance, but still requires restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. An S9 substance is prohibited, which makes access extremely restrictive and very difficult if not impossible to access in some states. S8 still has controls to prevent diversion and illicit use and still allows for very strict controls on access to the substance.

proposes adequate use of site security to restrict access, detailed inventory control and reconciliation records and appropriate standards for quality and safety

(please refer below for further details). In addition S8 has other therapeutically used-substances which have risk of addiction or criminal diversion. Rescheduling cannabis and THC as a S8 substance will allow appropriate access to more Australian people for therapeutic use who need it and this in turn will increase demand and promote a profitable operation with adequate growth potential for

Canada and United Nations (UN) Compliance

The UN office on drugs and crime has three main international drug control conventions: the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The Convention on Psychotropic Substances of 1971 is the primary international drug convention referenced at a federal level for cannabis. The convention focus on preventing the diversion of drugs into the illicit traffic. The convention allows for the cultivation of cannabis for medical, scientific and takes into account traditional licit use. Member countries of the UN (including Australia and Canada) are bound to this convention, and therefore decriminalization of cannabis (e.g., for recreational use) on a federal or national level, could jeopardize the UN status of such a country.

The Canadian federal model for medical cannabis seems to be the most compliant program taking into consideration UN obligations and the requirements to cultivate and manufacture high quality finished product against recognized pharmacopoeia. The federal model is regulated under the *Marihuana for Medical Purposes Regulations (MMPR)* and does not violate the UN convention on account of the allowance being for medical purposes. In Canada, the MMPR came into effect on April 1, 2014, and were intended to replace the *Marihuana Medical Access Regulations* (MMAR). Under the former system of the MMAR, persons could apply for a permit to possess cannabis from Health Canada within a doctor's supervision, and cannabis could be purchased from the Canadian Government (seeds or finished product). Under the MMAR, a person could chose to grow enough product within their own residence to satisfy their own needs, or else designate another grower to grow cannabis on their behalf. As a result, many of such "designated growers" spread across the country, which became a public safety concern given the limited oversight of this program. As a result, the Harper Government introduced the MMPR to effectively replace the MMAR, the former being a major overhaul and requiring product to be grown and distributed through large-scale commercial growers (called "licensed producers").

With the legalization of cannabis production, concerns of potential related criminal activity may arise. This area was touched on in the regulatory impact analysis statement published in the *Canada Gazette Part I*. In the analysis of the beneficial impacts of the MMPR, the risks associated with residential cannabis cultivation, as was permitted under the MMAR, such as potential home intrusions by criminals and the risks of sustaining serious injury or death in such a case was examined. The focus of the security impacts was on the risk and consequences of home invasion, violence targeting residential production involved in misuse, and criminal activity related to cannabis distribution on the illegal market.

It was noted that much of the societal risk and burden created by the MMAR was due to the

indirect impacts of allowing individuals to produce cannabis at home. They indicated that by shifting the production of cannabis for medical purposes from seldom-inspected private homes to more rigorously regulated, secure licensed producers, these impacts would be significantly reduced or altogether eliminated.

Rescheduling Benefits

Rescheduling cannabis and THC as a S8 substance will allow appropriate access to more Australian people for therapeutic use who need it and this in turn will increase demand and promote a profitable operation with adequate growth potential for who proposes to submit an application to the Health Secretary for a general license to cultivate and manufacture medicinal cannabis in a single facility in the State of Victoria for people to be treated under exceptional circumstances. Medical Cannabis licenses should not be easily obtainable. Applicants will have to prove that they have done their due diligence, submit detailed security plans, prepare stringent inventory control and reconciliation procedures, have high standards for finished product quality and safety and pass security clearance checks.

estimated the number of persons that will gain medical approval to possess cannabis in Australia based on the Canadian government's estimates. Health Canada estimates that in Q4 2017, there will be approximately 80,000 Canadians with medical authorization to use cannabis products. (Health Canada expects that number to increase to approximately 300,000 Canadians by 2024.). Based purely on the relative populations of Australia and Canada, as well as the rescheduling of cannabis and THC to S8, we estimate that by late 2017, there will be 53,000 medical cannabis users in Australia. Apportioning this to Australia's population, we can expect up to 200,000 potential patient clients within 10 years.

Our medicinal clients will probably be in one of the following categories:

- Children afflicted with epilepsy with a non-responsiveness / adverse reaction to pharmaceutical drugs.
- Adults with severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side effects which are intolerable for the patient
- Adults with terminal illness, focusing on improving quality of life, and symptoms such as pain, nausea and vomiting
- Severe pain, nausea, vomiting or wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
- Adults with chronic and severe pain, particularly as a result of nerve damage
- Adults suffering from muscle spasticity due to multiple sclerosis

Risk of Diversion and Illicit Use Scheduling considers the degree of risk and the level of control required over availability to protect consumers. Access restrictions to mitigate the potential for risk to public health and safety should include a prescription to use and possess medical cannabis; and physical security and inventory control at the site of cultivation and manufacturing. Cannabis including THC should be stored in a secure way and used under the prescription of an authorised medical practitioners to mitigate diversion and illicit use.

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To: Medicines Scheduling

Subject: Submission regarding the proposed amendments to the Poisons Standard for cannabis and cannabinoids

Date: Friday, 19 February 2016 12:35:27 AM

Attachments: cannabis .docx

Dear Sir/Madam,

I support the proposed amendment to the Poisons Standard for cannabis and cannabinoids for ACMS meeting March 2016.

The use of cannabinoid products for therapeutic use in Australia is likely to increase in coming years. There are a number of clinical trials currently underway to evaluate benefit.

There is a proportion of patients who request cannabis for symptom relief, but due to the current legislation are not able to obtain this legally. This complicates clinical practice, as some of these patients use cannabis or cannabis products obtained illicitly and their treating team are unaware.

The availability of cannabis and cannabis products for therapeutic use under Schedule 8 will allow for regulated prescribing and use, either through a clinical trial, or as further evidence emerges in clinical practice.

The change in scheduling will also facilitate world class research to evaluate cannabis and cannabis products for therapeutic use.

