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]

To: [redacted]

Subject: Medicines Scheduling

Date: consultation-proposed-amendments-poisons-standard-acms-and-accs-meeting-march-2016-coversheet - Invitation to edit

Friday, 5 February 2016 12:22:35 PM

[redacted]

[redacted]

Will also send a simplistic slideshow, summarizing why I believe cannabis is a safe and therapeutic substance for many serious diseases..(done for a dyslexia MP, so very simple, hopefully you can get ref for Pubmed /PMID from notes, to access abstract.

I am now about to do a safety and efficacy summary of the medical options I have been told I must take while cannabis is still illegal.

The contrast is why I want to go from Medical to Herbal therapies..it's the only ethical option in my opinion.

Thanks for being open to this information.

[redacted]

[redacted]

Subject: FW: Proposed amendments to Cannabis scheduling: comments
Date: Sunday, 21 February 2016 2:51:02 PM

[redacted]

Dear Sir/Madam,

I am hoping you will accept this submission for the proposed amendments on behalf of [redacted]

[redacted]

Sent: Thursday, 18 February 2016 6:17 PM

[redacted]

Subject: Proposed amendments to Cannabis scheduling: comments

[redacted]

Thank you for giving me the opportunity to comment on the proposed amendments to the scheduling of cannabis products.

Please find my comments attached to this email.

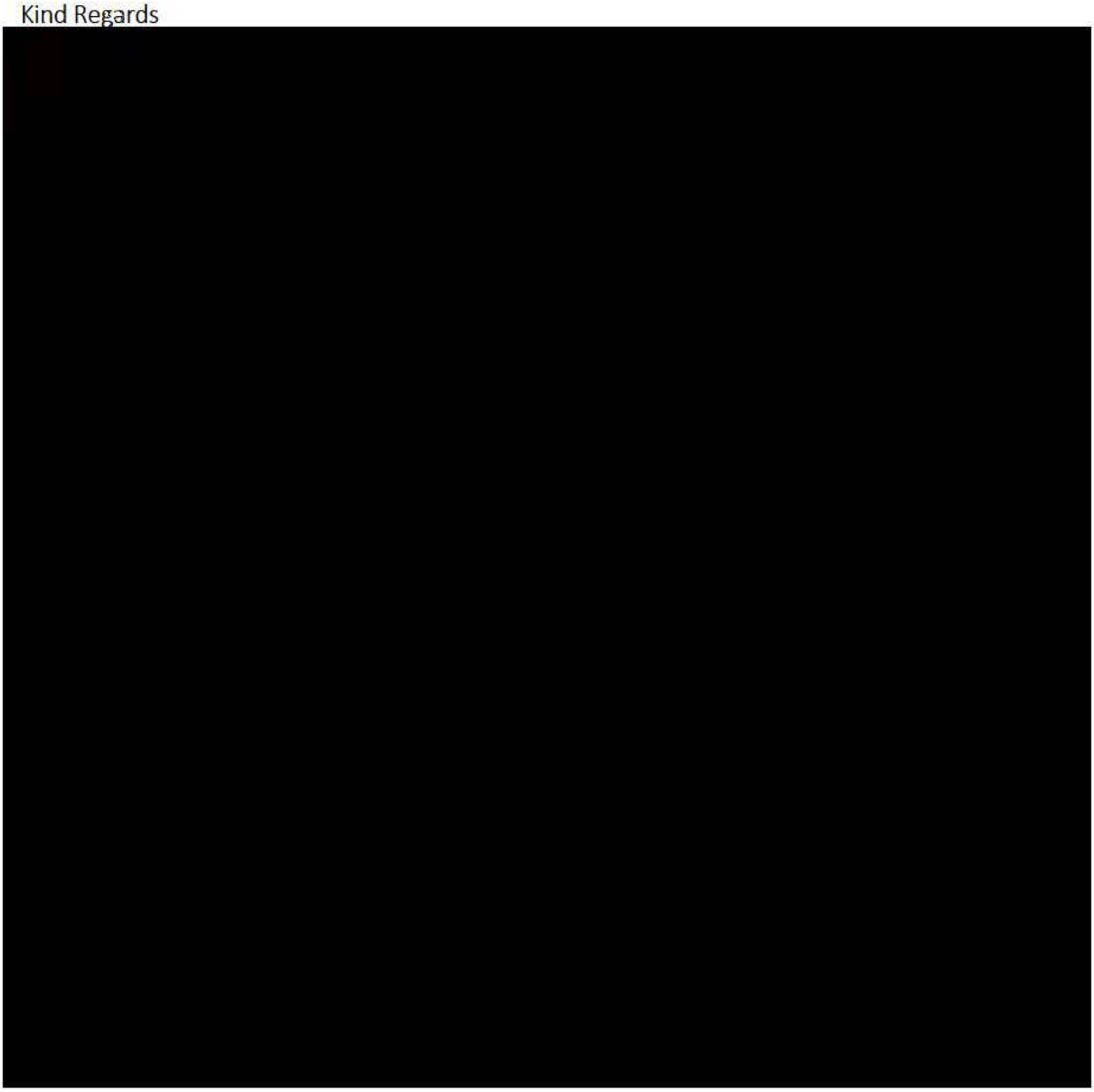
My comments are coming from:

1. a desire to postpone any amendment to the scheduling of cannabis products until after proper trials (dose finding, safety and efficacy) have been conducted.
2. an understanding that the storage, handling and transport of cannabis products should be the same as for Schedule 8 medications
3. an acceptance that individuals who chose to access cannabis products for therapeutic indications should have access to these products where they have been prescribed for that individual by an authorised specialist physician without fear of legal recrimination.

Please feel free to contact me [redacted] if you would like to discuss further this with me.

Again, thank you for the opportunity to provide comment on this proposal.

Kind Regards



[redacted]

Therapeutic Goods Administration

Comments regarding the use of cannabis and cannabinoids and the rescheduling of this plant and derived products.

There is an exceedingly large body of work devoted to the study of cannabis and cannabinoids. In the Article " The Therapeutic Potential of Cannabis and Cannabinoids" is listed 24 References and 119 electronic references pertaining to the studies of the therapeutic use of cannabis and cannabinoids. Including numerous trials already conducted. The TGA should defer to this large body of work already conducted.

I welcome the rescheduling of Cannabis and Cannabinoids from schedule 9 substance to a schedule 8 substance. The therapeutic use of cannabis should be regulated by General Practitioners.

There is no need to appoint authorised Practitioners only. This would induce bias and there is already a profound amount of bias already in the medical and political landscape when concerning this plant. This bias has derived mainly from the prohibition of Cannabis in the United States under the order of President Nixon who was not concerned with the medical uses of cannabis but rather his racist war on African and Mexican Immigration into the United States. And more generally the war on cannabis has stretched into the "War on the Poor". By far the highest use of Cannabis and Drugs generally is by people of lower socio-economic status, as outlined in the article the social determinants of drug use.

Cannabis is a safe alternative to many other medicines including legal and illegal. And gives people of lower socio-economic an exit from other exceedingly dangerous drugs including alcohol, nicotine, heroin and amphetamines.

Currently there are a large amount of people who are currently using this medicine and are considered criminals when the actual amount of their criminality is nil. The damage from cannabis is very low, lower than even legal drugs like nicotine and alcohol.

Thank You

[redacted]

References:

The Therapeutic Potential of Cannabis and Cannabinoids

Franjo Grotenhermen, Dr. med.1 and Kirsten Müller-Vahl, Prof. Dr. med.*,2
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3442177/

SOCIAL DETERMINANTS OF DRUG USE Catherine Spooner and Kate Hetherington Technical Report Number 228 ISBN: 0 7334 2244 6 ©NATIONAL DRUG AND ALCOHOL RESEARCH CENTRE, UNIVERSITY OF NEW SOUTH WALES, SYDNEY, 2004
https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/TR.228.pdf

[redacted]

22/01/2016

To Whom It May Concern,

[redacted]

Medicinal Cannabis Oil needs to be legalised and available for people like [redacted]

[redacted]

[redacted]

[redacted] intense pain like the beginning of a cramp that never goes away, make life miserable; causes depression and an inability to hold down a job.
Cannabis oil changed all that for [redacted] use 2 different strains. [redacted]

I want to speak to this section of the proposed changes.

"Options for additional controls ..

•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"

Why? Cannabis is NOT a poison!! By definition, a 'poison' can kill you.
1.a substance that is capable of causing the illness or death of a living organism when introduced or absorbed.

It is IMPOSSIBLE to kill yourself by overdosing on cannabis OR the extracted oils. (you can sure THINK you are dying but you aren't) So, why make restrictions like 'only on Dr prescription'? That is pandering to the false claim that there are 'harmful effects' to the use of the plant.
Ok, there are a couple of issues. Paranoia and bad trips where you have some really scary hallucinations. There are some strains that do cause those issues, but they are KNOWN side effects with known antidotes.
This brings me to the point of where cannabis needs to fall in your schedule.A complementary medicine.

A complementary medicine is defined in the Therapeutic Goods Regulations 1990(link is external) as a therapeutic good consisting principally of one or more designated active ingredients mentioned in Schedule 14 of the Regulations, each of which has a clearly established identity and traditional use: Cannabis has a 4000year traditional use history, with not a single death.

Recently, there have been some deaths from synthisized THC, but there has never been a recorded death from the use of natural cannabis or it's extracts.

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.

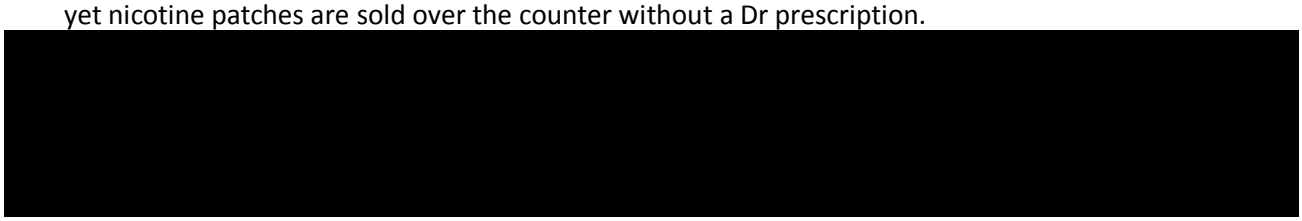
HOWEVER the moment you want to sell some of that wine you require a license and to show quality control and safety for human consumption.

On a less popular note, the same should apply to tobacco. [redacted] to be consistent .Except that tobacco is a proven carcinogen and cannabis is an ANTI CANCER treatment. Nicotine is a poison that CAN kill in high doses, cannabis can NOT.

Nicotine is deadly.."In large doses it produces nausea, vomiting, sweats and great muscular weakness.The alkaloid nicotine is a virulent poison producing great disturbance in the digestive and circulatory organs. It innervates the heart, causing palpitation and cardiac irregularities and vascular contraction, and is considered one of the causes of arterial degeneration.Nicotine is very like coniine

and lobeline in its pharmacological action, and the pyridines in the smoke modify very slightly its action.Tobacco was once used as a relaxant, but is no longer employed . Its active principle is readily absorbed by the skin, and serious, even fatal, poisoning, from a too free application of it to the surface of the skin has resulted."

yet nicotine patches are sold over the counter without a Dr prescription.



[redacted]

- Please change the scheduling of Cannabis and cannabinoids to Schedule 8 entries for internal human therapeutic use, but restrict access by creating an entry such as "Poisons available only from or on the order of a specialist physician."

  My reasons for this are that [redacted] endures the limitations and suffering of [redacted] now has additional problems because of the use of [redacted] and no relief from pain. [redacted]

  I do not want Cannabis to be easily accessible for recreational use.

  [redacted] experienced the restrictions and cautions around obtaining [redacted] These were humiliating and sometimes inconvenient [redacted] but were helpful in keeping [redacted] on track towards reducing the dosage, until ultimately coming off the medication.

  [redacted] life is profoundly restricted by [redacted] pain. [redacted] mental health is very negatively affected. [redacted] has suffered this condition [redacted] and doctors were very slow to respond to and diagnose [redacted] condition. [redacted] is unable to work, although [redacted]

  I do not know if THC will enable [redacted] to live a pain free and active life, but [redacted] have the opportunity to trial the medication. If it works [redacted]. If it doesn't work [redacted] will be no worse off than [redacted]

  Thank you for your consideration of this matter.

  Kind regards

  [redacted]

[redacted]

[redacted]

Cannabis Rescheduling Proposal

Questions and Answers

[redacted]

Cannabis Re-scheduling proposal- questions and answers

21 January 2016

What is proposed?

It is proposed that the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP or the Poisons Standard) be amended to place some cannabis- derived substances, when used in particular ways, in Schedule 8 of the Standard.

Potential down-scheduling to S8 still allows very strict controls on access to the substances. A number of other therapeutically used- substances which have risk of addiction or criminal diversion such as cocaine or morphine is also included in schedule 8.

Cannabis and THC (a psycho –active component of cannabis) currently sit in Schedule 9,

Which means access for their use is extremely restricted.

Proposal:

Due to corruption, propaganda and racism in the highest order of society, as well as the fear of losing billions of dollars in timber, [redacted] cotton, pharmaceuticals etc, investees such as, [redacted] were responsible for the prohibition of hemp in the 1930's. Because of these unjust laws, Cannabis should now become legal, and re-classed as a Schedule 4 not a Schedule 8 drug. The reasons being;

1) Cannabis crosses the Blood Brain Barrier in small amounts, unlike heroin, which is legal, crosses the Blood Brain Barrier rapidly, enabling the host to forget to breathe, thus, the risk of over-doze and death.

2) Synthetic Opiates are supposed to be restricted legal drugs but are distributed by doctors at alarming rates to cure pain, and other ailments such as anxiety. Doctors are paid and encouraged by big pharmaceutical companies to push their drugs on to vulnerable, sick people within the

community. “Due to easy accessibility of drugs, doctors, pharmacists, nurses and other health professionals are at greater risk for drug abuse.” (Bryant, B, Knights, K, Salerno, E, 2003, pg.357).

3) “Synthetic Opiates drugs are supposed to be for short term use only”. (Tiziani, A, 2006, pg.571). Unfortunately, this policy is being abused by doctors and pharmaceutical companies, who are lawfully getting people hooked on these drugs. The victims are those who are doing time within correctional facilities and nursing homes. [redacted] patches have to be checked regularly on elderly residents, within hospitals and nursing homes, as visitors or nursing staff have been known to steal them off residents.
(Bryant,B,Knights,K,Salerno,E,2003,pg.357)

4) There is the risk of addiction with every drug ever prescribed on this planet. However, due to the human nervous system, cannabis is the only in-patentable substance on this earth that binds on Synaptic Nerves within the brain and central nervous system. The risk of addiction depends on the scenario the person is experiencing at that moment in time, the support that person is receiving, and the coping mechanisms within that person’s thoughts. The side effects of cannabis are minimal compared to addiction from heroin, cocaine, alcohol, synthetic opiates, benzodiazepine, risperdone and others.

5) Paracetamol can be bought over the counter and in supermarkets. Paracetamol is an analgesic, anti-pyretic but has no useful anti-inflammatory properties. (Tiziani, A, 2006, pg.9).
6) Paracetamol is readily given out to residents within nursing homes for no good reason. Paracetamol,over time, has potential to destroy kidneys and liver through elimination.

[redacted]

[redacted]

Why is this being proposed?

On 17 October 2015, the Commonwealth Government announced that it will seek parliamentary approval of amendments to the Narcotic Drugs Act 1967 to establish a national scheme to allow the cultivation of cannabis for medicinal purposes. However, the access to these products-including handling, transportation and storage- is controlled by their schedule 9 of the Poisons Standard which makes supply of product grown and manufactured in Australia very difficult and, in some states, potentially impossible. This scheduling proposal **complements the planned amendments to the Narcotic Drugs Act** and aims to simplify access for those qualified for such access, while keeping appropriate controls in place to prevent these products from being diverted to illicit uses.

Comment:

- It has become quite obvious that due to public opinion, and the discovery that medical cannabis has been proven to cure cancer, mental health illness, multiple sclerosis, glaucoma and other neurological disabilities, the Commonwealth Government has been encouraged to legalise medical cannabis.
  Medical cannabis is not just for medicinal purposes, hemp is also the world's only fastest growing bio-mass, and can be made into fuel and textile.
- Changing medical cannabis to a schedule 4 will give Australians the benefits of using this product to its full potential, fuel, textile and health tonic. The Australian Government has allowed [redacted] drug companies to grow, harvest, package, transport, and sell opiates for many years. Medical cannabis should be no different.

- Government has plenty of land space in all states, and there are plenty of resources for growing, harvesting, packing and selling medical cannabis. Federal Government should be encouraging willing people with in the communities in each state to grow, package, and sell medical cannabis.

- Transportation, packaging and dispensing of medical cannabis should be no different to any other company or organisation interested in growing produce in Australia, for Australians.

[redacted]

[redacted]

- Australian Governments should not give grow rights, or any other rights of medical cannabis to big polluters, such as [redacted] and other toxic pharmaceutical companies, who have already made billions of dollars with their toxic drugs killing and ruining lives of billions of people with their products within the general public.

What is the scheduling process?

Scheduling is the national system for applying access restrictions on human and veterinary medicines as well as a range of chemicals where there is a potential risk to public health and safety. Substances are scheduled according to the degree of risk and the level of control required over availability to protect consumers.

While decisions on medicines scheduling are made by a delegate, who is a senior medical officer, in the Commonwealth Department of Health, the implementation of scheduling decisions is the responsibility of state and territory governments. The state and territory government are responsible for imposing legislative controls on the supply of substances and the controls these governments impose usually flow from the schedule in which the poison is located.

The policy is outlined in the **Australian Health Minister's Advisory Council Scheduling Policy Framework (//www.tga.gov.au/publication/ahmac-scheduling –policy-framework-medicines-and chemicals).**

The proposal will be referred to the Advisory Committee on Medicines Scheduling (ACMS) for advice and after publication on the TGA website today (21 January 2016), public comment is invited (//www.tga.gov.au//consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-and-accs-meeting-march-2016) prior to committee consideration by close of business 18th February.

After the Committee considers the re-scheduling proposal, public comment and background papers, they will provide a recommendation to the senior medical officer.

[redacted]

[redacted]

Opinion:

Before prohibition, medical cannabis was used for thousands of years, throughout the world, for fuel, textile and health tonic. Medical cannabis has already proven to be non-toxic, and not a potential risk to public health. Unlike approved prescription medications which have potential to cause more mental health illnesses, side effects and even death to the general public. Not just through overdose, but through accidents as well. Anti-psychotic ,anti-epileptic and anti-depressant drugs damage brain impulses due to the fact that they don't bind on synaptic nerve endings like cannabis does; but also, block other neurotransmitters such as dopamine within the brain and central nervous system, disabling movement, speech as well.

Does this public notice mean that substances derived from cannabis will definitely be down-scheduled?

No. The scheduling decision will be made by a senior medical officer (in the capacity as a delegate of the Secretary of the Commonwealth Department of Health). Comments are being sought prior to a meeting of the Advisory Committee on Medicines Scheduling in March 2016.

The Committee is made up of independent experts as well as state and territories representatives that provide advice to the scheduling delegate. The scheduling delegate will make an interim decision based on the comments made and the advice from the Committee.

Comment:

There is enough evidence out there now, though social media, documentaries on [redacted] television, to see that there are many benefits in re-scheduling medical cannabis to schedule 4. Medical cannabis should be legalised for all its properties. It is a well known fact that oil prices have dropped on the stock exchange because of global warming. Australia needs to invest in medical cannabis for this reason too. By re-scheduling cannabis to schedule 4, for fuel, textile and health tonic, cannabis will create new jobs, as well as, provide working towards a decline in green house gasses. The use of hemp for fuel and textile will help clean up our environment. There is also the fact, according to [redacted] Australia is the hottest country in the world. The Government need to start with cannabis as a clean change for the future.

[redacted]

[redacted]

What is the role of states and territories in this?

An entry into the Poisons Standard has no legal effect unless it is adopted through state and territory drugs and poison legislation. If approved, the proposal aims to support a consistent approach that all states and territories can apply to allow the supply of medicinal cannabis in their jurisdiction. It will be up to the individual states and territories how they might wish to implement any final decision.

Why can't the Therapeutic Goods Act 1989 be used to guarantee a consistent approach to supply of medicinal cannabis products?

The role of the Therapeutic Goods Act relates to the regulation of the supply of therapeutic goods and works in tandem with state and territory legislation on the access to scheduled particular substances. This proposal is designed to facilitate the access to scheduled particular substances. This proposal is designed to facilitate the access pathways already available under the Therapeutic Goods Act for un-registered products.

The Therapeutic Goods Acts makes provision for the use of un-registered medicines in certain cases where there is medical opinion that is justified, such as through the Authorised Prescriber Scheme, where a medical practitioner can be authorised by the TGA to prescribe a specific medicine to a specific patient group.

It also allows for the conduct of clinical trials, which are necessary to test new medicines to enable them to be registered by the TGA for general use.

When will a decision be made?

Following the meeting of the ACMS in March, an interim decision will be published seeking further comment. A final decision would then be made before the end of May 2016 and published with an implementation date, if appropriate. However, implementation of the decision in individual states and territories will depend on when and how the decision is adopted into state and territory legislation.

[redacted]

Designated active ingredients

1) **Medical Cannabis- An amino acid**- An amino acid is a neurotransmitter in the spinal cord. Due to prohibition, there has been no testing on cannabis, so it is unknown if it contains amino acid**.** Scientists have discovered that medical cannabis does contain Dopamine, a neurotransmitter necessary for the brain and central nervous system as it promotes movement. This could possibility mean that medical cannabis does contain amino acid. (Harris,P,Nagy,S,Vardaxis,N,2006,pg.77)

2) **Medical Cannabis-Charcoal-** It is uncertain that medical cannabis contains charcoal.

3) **Medical Cannabis-A choline salt.** There was no listing in Mosby's dictionary for choline salt, but there is a listing for choline and choline esters. Choline, is a lipotropic substance that can be synthesised by the body. It is considered by some to be essential under certain circumstances. Found in most animal tissues, choline is a primary component of acetylcholine, the neuro transmitter, and functions with inositol as a basic constitute of lecithin. It prevents fat deposits in the liver and facilitates the movement of fats into cells. The richest source of choline is in the liver, kidneys, brains, wheat germ, brewer's yeast and egg yolk. Due to prohibition, there have been no tests carried out in Australia, on medical cannabis for choline, or for any other vital neuro-receptors. There is also a possibility that medical cannabis does contain choline due to these presenting properties.

   (Harris, P, Nagi, S, Vardaxis, N, 2006, pg.356-357)

4) **Medical Cannabis-An essential oil-** When converted to oil, cannabis has proven to be an effective for the treatment of epilepsy and Dravet syndrome in children. Cannabis oil may also have potential to heal skin cancers and other skin conditions. Medical Cannabis can also be used to make delicious, healthy edibles as well. Before prohibition, Cannabis oil was used as a source of light in oil lamps.
   Cannabis is also used as an antiemetic for some cancer patients.

5) **Medical Cannabis-Plant or herbal material (or a synthetically produced substitute for material of that kind) including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll**

Medical cannabis is a plant with many properties. Its buds and stems serve as a healing herb, but can also be converted to a safer combustible as well. In the 1930s scientists found over 25ooo uses for cannabis, ranging from dynamite to cellophane paper. Medical cannabis should be used in whole plant form. Herbalists have tried to replicate medical cannabis by adding a few of the legal neuro receptors such as anandamide and dopamine to their synthetic medical cannabis; as a result, people have experienced side effects due to this product not containing THC, and other undiscovered neurotransmitters this plant has. Synthetic medical cannabis should be avoided because of this fact. The evidence on the news about the bus driver is a good example. Due to cannabis being an in-patentable herb, it is impossible to replicate all the properties it has.

6) **Medical Cannabis-A homeopathic preparation.**

"A homeopathic preparation is classified as a system of therapeutics based on the theory was advanced in the late 18th century by Dr. Samuel Hahnemann, who believed that a large amount of a particular drug may cause symptoms; of a disease and moderate dosage may reduce those symptoms. Thus, some disease symptoms could be treated by very small doses of medicine". (Harris, P, Nagy, S, Vardaxis, N, 2006, pg.831).
"In practice, homoeopathists dilute drugs with milk sugar in ratios of 1to 10 to achieve the smallest dose of a drug that seems necessary to control the symptoms in a patient, and only prescribe one medication at a time." (Harris, P, Nagy,S, Vardaxis,N,2006,pg.831).
There is also the fact that medical cannabis has been used in countries to wean people off alcohol and harder drugs.
(Bryant, B, Knights, K, Salerno, E, 2003, pg.380-81)

7) **Medical Cannabis-A microorganism, whole or extracted, except a vaccine**

Due to prohibition in Australia, medical cannabis micro-organisms are un-known.

8) **Medical Cannabis-A mineral including a mineral salt and a naturally occurring mineral**

Due to prohibition, it is unknown whether medical cannabis is an occurring mineral.

9) **Medical Cannabis-A mucopolysaccharide**

The definition of a mucopolysaccharide is much or many mucus containing hexosamine and sometimes occurring with protein such as mucins.
A hexosaminidase test is a blood test to detect Tay-Sachs disease and Sandhoff's disease, a variant of Tay-Sachs.
Definition of Tay-Sachs disease- "A neurodegenerative disorder of lipid metabolism caused by a deficiency of the enzyme hexosaminidase A, which results in the accumulation of sphingolipids in the brain." (Harris,P,Nagy,S,Vardaxis,N,2006,pg.1679). "The condition which is transmitted as an autosomal- recessive trait occurs predominantly in families of Eastern European Jewish origin". (Harris,P,Nagy,S,Vardaxis,N,2006,pg.1679). With these symptoms affecting the neurological system, there is a big possibility that medical cannabis may relieve the symptoms of these diseases.

10) **Medical Cannabis-Non human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates.**

Medical Cannabis is not suited to be synthetically altered due to the make-up of various neurotransmitters it possesses. As discussed previously, cannabis should be sold as an antidote for synthetic drugs, in its purest form.

11) Medical Cannabis-A lipid, including an essential fatty acid or phospholipid.

Cannabis is a lipid which is stored in the kidneys.

12) Medical Cannabis-A substance produced by or obtained from bees, including royal jelly, bee pollen and propolis

Due to prohibition it is un-known

13) Medical Cannabis-A sugar, polysaccharides or carbohydrates

Due to prohibition it is un-known

14)Medical Cannabis-A vitamin or provitamin

Due to prohibition, it is un-known.

Bibliography

Bryant,B,Knights,K,Salerno,E, 2003,"Pharmacology for health professionals"Elsevier,Marrickville, N.S.W, Australia

Harris,P,Nagy,S,Vardaxis,N,2006,"Mosby's Dictionary,"Elsevier,Marrickville, N.S.W, Australia.

Tiziani,A,2006,"Harvard's Nursing Guide To Drugs seventh edition,Elsevier, Marrickville,N.S.W. Australia.

CANNABIS SAFETY ANALASYS

There has never been a time in the world when people have been aware and trained in safety and risk assessment. There are more people than ever before trained to save a life, assess the risk to themselves and step in and save lives. There are people in all industries carrying out risk assessments on a daily basis or it could be for every job they carry out with the main consideration always being people's health and wellbeing. [redacted]

Part of safety is being able to assess risks and when it comes to cannabis there is a growing trend backed by science where the public are assessing cannabis safer than alcohol, safer than caffeine, safer than Aspirin and a recent US poll showed that Americans believe cannabis is safer than sugar.

If the safety analysis, [redacted] use as a benchmark is not based on the unbiased truth then any standards or regulations that [redacted] apply do not meet any minimum standard of safety and any comparison for efficacy cannot be considered with safety of the person as the primary objective.

Australians have been traveling in large numbers for a quarter of a century to places like Nepal, India, Morocco, Amsterdam and Spain where cannabis is mostly accepted in society and they mainly use hashish, high THC resin as they have done in some places for centuries. Most Australians travel to or know someone that has travelled to those places specifically for that reason and seeing first hand that life goes on as normal with cannabis in the society and the only crazies are the excited tourists. Australians have experienced firsthand that high amounts of THC in the community does not pose the risk that the ill-informed keep threatening is the impending danger to the community.

The internet allows people to access information at the palm of their hand and developments overseas like the recreational and medicinal laws in the US, The Uruguay government selling cannabis for less than the black market and with media reports of positive trends and outcomes around the world. This is validating and vindicating the risk assessment perceived by the community and confirming the discrimination against cannabis is real and its promoted dangers and unknown risks are false. The Harvard study 2013 that shows no link with cannabis and schizophrenia and infact all of the dangers that the TGA makes its assessment on have been proven wrong or the complete opposite.

Cannabis Safety Risk Assessment

Cannabinoids are the only real compound in cannabis that are in question and even though there are many, it's only three or four types that are found in substantial amounts that warrant any form of consideration and thousands of independent studies fail to show long term harm from the main cannabinoids would indicate the trace cannabinoids pose no threat.

For this example we can put them in to categories where they share the same safety and sub profile attributes. Please refer to the table below and the Cannabinoid Groups 1-4

1. THCA/CBDA/CBCA/CBGA (Raw cannabis Non Decarboxilated Cannabinoids)
2. CBD/CBC/CBG (Non Psycoactive decarboxilated Cannabinoids)
3. THC/CBN Suppository (Mild to no psycoactivity effect)
4. THC/CBN Oral (Psychoactive Cannabinoids)

Risk Assessment tables next page:

Risk of Consumption Assessment Matrix

Risk is the combination of severity (impact) with the event probability (frequency).
The Risk Assessment Matrix is used to derive a Risk Indicator (RI) that must be used to quantitatively assess the risk of any substance being consumed

Risk Assessment Matrix

→Severity → ↓ Probability ↓	CATASTROPHIC (4)	CRITICAL (3)	MARGINAL (2)	NEGLIGIBLE (1)
FREQUENT (A)	HIGH	HIGH (3A)	HIGH (2A)	MEDIUM (1A)
PROBABLE (B)	HIGH (4B)	HIGH (3B)	MEDIUM (2B)	LOW (1B)
OCCASIONAL (C)	HIGH (4C)	HIGH (3C)	MEDIUM (2C)	LOW (1C)
REMOTE (D)	HIGH (4D)	MEDIUM (3D)	LOW (2D)	LOW (1D)
IMPROBABLE (E)	MEDIUM (4E)	LOW (3E)	LOW (2E)	LOW (1E)

Risk Assessment

Risk → ↓ Substance ↓	Side Effects	Addictiveness	Long Term Harm	Fatality Risk/Toxicity	Risk Score Total
Cannabinoid Group 1	LOW 1	LOW 1	LOW 1	LOW (1E)	4
Cannabinoid Group 2	LOW 1	LOW 1	LOW 1	LOW (1E)	4
Cannabinoid Group 3	MEDIUM 2	LOW 1	LOW 1	LOW (1E)	5
Cannabinoid Group 4	HIGH 2	MEDIUM 2	LOW 2	LOW (1E)	7
Caffeine	MEDIUM 2	MEDIUM 2	MEDIUM 2	HIGH (4C)	10
Aspirin	LOW 1	LOW 1	HIGH 3	HIGH (4C)	8
Cough syrup	MEDIUM 2	MEDIUM 2	MEDIUM 2	HIGH (4C)	10

Risk Assessment Summary

In this risk assessment it clearly demonstrates that all cannabinoid groups pose far less danger than common products sold in the supermarket. Doctors are going to face liable claims If we are going to have a system where the perceived danger of Cannabis is greater than Opiates and Oxycodone, where having a drug resistant condition qualifies someone for cannabis use.
Any Doctor will be in extremely dangerous territory when they refuse a patient cannabis and insists he takes higher doses of opiates or oxycodone. If a doctor refuses a patient a substance that is not lethal with no long term side effects and insists he takes a potentially lethal substance with known long term side effects, then the liability falls on the doctor for denying the patient the safest option first and putting them at unnecessary risk.

Community Expectation

There are not many people that believe that cannabis is more harmful than alcohol and there are more than enough studies that prove cannabis is far safer. People that use cannabis for the same therapeutic reasons that others use alcohol, that is to relieve stress and relax and those that choose cannabis are experience better health and social outcomes for their choice, then the TGA has a duty of care and legal relationship to ensure the best health outcomes. The TGA has a responsibility to recognise the potential benefit of allowing adults to use cannabis for stress relief and relaxation and the statistics speak for themselves in states where cannabis has been excepted and regulated.

Lost Revenue and negative community consequences

The lack of TGA regulation on adult use is also preventing the community from benefiting from the tax of the $5 Billion P/A cannabis black market and is ensuring that any adult restrictions are the blue print for a thriving black market. The consequences of not dealing with adult use has a detrimental effect on the community as the proceeds of crime are often used against the community. Because the TGA fails allow cannabis to be regulated, the Police treat it as an illegal substance and create laws with ought properly to demonstrate why the community has an obligation to obey those laws such as DUI and possession. Once recognised for Adult use the Police could do the proper due diligence and demonstrate with science behind the obligations the community has to abide by to ensure a safer community.

Cannabis for therapeutic Adult Use

Cannabis has been proven beyond doubt to be fare safer than alcohol, being a non toxic, non lethal substance with no long term side effects, there is absolutely no scientific or logical reason why Adults should be denied the use of cannabis for stress relief and relaxation.

The TGA needs to ensure that cannabis classification must include a mechanism for Adults to purchase cannabis as a therapeutic product from the pharmacy, the same as someone purchases other therapeutic products without script like Cough Syrup, Aspirin and Caffeine products that cannabis is far safer than.

Cannabis for Adult use could be sold in preparations for Oral ingestion or vaporizing in varying strengths. The pharmacy could be the distributor for a 1 year trial to determine if this is the best way forward regarding distribution.

Hello TGA.

Thank you for giving the public, the opportunity to provide information, to you!

First I will provide, a little bit of my history. Followed by my recommendations for the TGA!

[redacted]

when the problems began, every single prescription drug, has side effects, [redacted] they created suicidal/homicidal thoughts, and did NOT really relieve the pain. [redacted] They ALL suggested [redacted] cannabis, and stop the prescription drugs! After taking their recommendations [redacted] found a cannabis supplier, and began to utilise it! [redacted] the cannabis, does relieve 99% the pain, making life that little more livable. There was only one problem; it was the worry and paranoia, [redacted] informed the Medico's, who ALL told me, "It was the laws creating this situation"! What? They explained it this way- "Subconsciously. [redacted] know [redacted] breaking the law, and in turn, worry about that! [redacted] stop thinking [redacted] breaking the law, and the worries will disappear"! [redacted] Until, the Government began road side testing, and now the worries have returned! All due to the introduction of draconian laws! It has now been, [redacted] medical cannabis, and have never looked back, never had a driving accident in that time, and have never had any mental issues, at all!

Here is an internet link, to a peer reviewed article, printed in the Medical Journal Australia, stating what the Medical professionals recommend! (https://www.mja.com.au/journal/2015/202/2/medical-cannabis-time-clear-thinking). [redacted]

Here are my recommendations for the Poisons Standards, Amendments, and our Narcotic laws- First of all, cannabis (The [redacted] herb/plant and food) is NOT a poison, and should NOT be on any poison list, or be a schedule 8! Cannabis is also not a narcotic, and should be removed form that list too! At least, cannabis could be added to the "Complementary Medications list"!

Having cannabis listed as a poison, is very hypocritical, when Tomato and Rhubarb leaf, and green Potato's, Apple seeds, Apricot seed, Balsam Pear seed and rind, Avocado seed and unripe fruit, Walnut hulls, Cashew shell, Cherry seeds, Fig tree sap, Nectarine seeds, Peach pits, Pear seeds, Plum seeds, Sorghum, Asparagus, Eggplant, Elderberry, Fava bean, Horse bean, Some species of Rosemary and Sage, Wild Onion, Wild Parsnip, Lima beans, Cassava root, Nutmug, Kidney beans, are actually deadly to humans! While cannabis is NOT!

Thank you.

[redacted]

REGARDING :

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.

[redacted] lost count of the different medications [redacted] prescribed [redacted] prescribed anti-depressants due to it having a side-effect of relieving pain. Another side effect is loss of balance, [redacted]

[redacted]

With Marijuana, [redacted] helps to relax [redacted] muscles, as they spasm often. [redacted] not give in to the stress and anxiety that come with a disability. [redacted] to sleep, which is something that has been problematic [redacted]

Most importantly, there are NO side effects. ZERO.

[redacted] take medical Marijuana [redacted] manage [redacted] pain, and is 100% agreeable [redacted]

[redacted] problem is this: REGULATION of medical Marijuana.

[redacted] obtain it from a black market source, [redacted] no choice as to what type of Marijuana[redacted]. So instead of being able to take Cannabis oil (with THC removed) in the [redacted] cannot take anything. [redacted] can have some natural medicine in the form of Marijuana.

[redacted] get in the black market.

Not to mention the risks involved with non-regulation of the growth of the plant itself.

[redacted] pain levels will increase, [redacted] quality of life will slowly go downhill.

The ONE thing [redacted] that medical Marijuana WILL be legalised in the near future. [redacted]

This is why it is so important for this natural, miracle PLANT to be regulated and legalised.

Patients should not be punished, or forced to break the law, simply to gain some relief that the pharmaceutical drugs cannot provide.

I am proud to be Australian, yet the way the laws are in this country – punishing the sick, making criminals of [redacted] desperate to help[redacted] – makes me deeply ashamed. I honestly do not know or understand why or how this humble plant has been vilified and outlawed.

Allowing appropriate use and access of medical Marijuana is an urgent, lifesaving issue. And it needs to happen NOW.

Yours sincerely

[redacted]

[redacted]

Email: medicines.scheduling@tga.gov.au

Dear [redacted]

Re: Proposal to enable appropriate access to medicinal cannabis products by creating new Schedule 8 entries

Thank you for inviting comment on the current proposal to enable appropriate access to medicinal cannabis products by creating new Schedule 8 entries.

[redacted]

[redacted] position on the use of cannabis for patients with chronic non-cancer pain was published in April 2015 in the Statement on "Medicinal Cannabis" with particular reference to its use in the management of patients with chronic non-cancer pain (PM10) (Appendix 1). Specifically, [redacted] does not recognise a need for greater availability of medicines in general and in particular does not endorse the use of cannabinoids in chronic non-cancer pain until such time as a clear therapeutic role for them is identified in the scientific literature" (clause 10).

[redacted] acknowledges the proposal to align the scheduling of cannabis within the Poisons Standard with the expected amendments to the *Narcotic Drugs Act 1976*. [redacted] is concerned that this may well facilitate inappropriate prescribing of cannabis for therapeutic purposes without clear supporting evidence. Although the proposal highlights the strict controls that are placed on substances in schedule 8, inappropriate prescribing and diversion of these, especially opioids, remains a significant contemporary issue. In 2015, the Australian Commission on Safety and Quality in Health Care published the Australian Atlas of Healthcare Variation. (http://www.safetyandquality.gov.au/atlas/chapter-5-opioid-medicines/) Chapter 5 in that publication, Opioid Medicines, identified a wide variation in prescribing of existing schedule 8 opioid medications. This variation is likely to reflect the twin influences of socioeconomic factors and inadequate primary care capacity on the management of pain, resulting in inappropriate prescribing of opioids.

[redacted] continues to promote better prescribing of opioids, through the *Better Pain Management* online learning resources program developed to support prescribing by primary health care professionals (http://www.fpm.anzca.edu.au/resources/better-pain-management), through the Recommendations regarding the use of opioid analgesics in

[redacted]

patients with chronic non-cancer pain - 2015 (PM01) (appendix 2) and by advocating for appropriate regulation in Australia and New Zealand.

In the event that cannabis preparations are down-scheduled to schedule 8 of the poisons standard, [redacted] would strongly support additional controls on these substances being imposed through an entry in Appendix D, specifically that the availability of cannabinoids for patients with chronic non-cancer pain be restricted to prescription by specialist pain medicine physicians.

Thank you for taking the time to review this submission. For further information, please contact [redacted]

Yours sincerely

[redacted]

Recommendations regarding the use of Opioid Analgesics in patients with chronic Non-Cancer Pain

PURPOSE

[redacted] recognises the lack of definitive evidence supporting the long-term effectiveness of opioid analgesics in people experiencing chronic non-cancer pain (CNCP) and the substantial evidence of potential harm. This document outlines the current position of the [redacted] regarding opioid use in CNCP. It is anticipated that this position will evolve as the evidence base develops.

CURRENT EVIDENCE

The efficacy of opioid therapy is supported by strong evidence from randomised controlled trials in acute pain [1] and from systematic reviews in cancer pain [2,3], palliative care [4] and opioid dependency/addiction [5]. In CNCP systematic reviews report modest short term analgesic benefit [6,7]. However the duration of the RCTs reviewed (up to 4 months) was too short to adequately inform the long term role of opioid treatment in CNCP.

A recent systematic review that examined the evidence of long term opioid efficacy and risk [8] concluded that “evidence is insufficient to determine the effectiveness of long term opioid therapy for improving chronic pain and function”. There is also a dose-dependent risk of serious harms especially when opioids are combined with other psycho-active agents including alcohol.

Tolerance [9,10] and other adverse effects are potential limiting factors with long term opioid use. A systematic review of opioid response after 6 months of therapy in 25 non-randomised case series showed weak evidence of modest analgesic benefit and inconclusive data in regard to improvement in physical function and quality of life [11]. Population studies show that people maintained on long term opioid therapy for CNCP describe more troublesome pain and greater functional interference than people not on opioids [12]. A recent Australian population study examined a cohort of patients on long term opioid therapy and found that two-thirds were unemployed or receiving a government benefit and almost half had low income [13]. In addition, 80% of the cohort reported multiple pain conditions, 50% significant depression, 50% suicidal ideation, over 50% a history of childhood abuse or neglect and over 30% had a lifetime alcohol use disorder. Such associations illustrate the complexity of the phenotype of CNCP and highlight the need for multidisciplinary assessment and management.

Clinical experience and multiple studies have indicated that the use of high pain severity ratings is a poor basis for selection of patients for opioid prescription. Pain ratings are well-known to be influenced by multiple psychological and contextual factors [14,15]. Patients with mental health and substance abuse problems are more likely to be prescribed chronic opioid therapy (“adverse selection”) and at higher doses than people without those risk factors [16]. Once established, dependence on opioids makes it hard to wean and cease them despite lack of analgesic benefit [17].

Accumulating evidence highlights the adverse effects of opioid therapy. Falls, cognitive impairment and gastrointestinal problems are well recognised clinically but have not been well studied over the long term [8]. Better documented risks include opioid misuse and addiction [18,19], overdose and death [20,21,22], sleep apnoea [23,24,25], sexual and other endocrine dysfunction [26,27,28], driving impairment [29,30,31,32] and opioid prescription to manage psychological distress (the “chemical coper”) [33]. An additional concern is that many patients on long term opioid therapy are co-prescribed benzodiazepines and the combination of these, potentially with other sedatives and alcohol, is associated with a further increased risk of apnoea and death [20, 34].

Screening for opioid risk has been recommended but at this point evidence of effectiveness is lacking. Screening for high risk patients, treatment agreements and urine testing have not been shown to reduce overall rates of opioid prescribing, misuse, or overdose [35]. Newer strategies aimed at reducing the risk of opioid misuse require evaluation. These include more selective prescription of opioids, avoidance of additional sedative hypnotics, prescription of lower doses, tamper resistant formulations [36,37] and prescription monitoring programs [35].

It is clear that opioid pharmacotherapy cannot be considered to be a core component of the management of CNCP. Furthermore, issues of patient selection and duration of opioid therapy require further definition.

A focus on pain relief alone via the passive receipt of opioid therapy can distract both patient and prescriber from active self-management strategies. This raises the question of suitable therapeutic alternatives, an issue that remains only partially resolved given the modest gains reported from cognitive behavioural approaches [38,39]. Clearly there are challenges in systematically reviewing studies with different treatment components and methodologies. Not all cognitive behavioural programs are the same. Hence the content and quality of multidisciplinary programs need further examination. Nevertheless, the benefits of the multidisciplinary approach are highlighted by studies showing improvement in pain and physical and emotional functioning after opioid cessation in a cognitive behavioural pain management program [40,41] Strategies showing promise as components of the evolving multidisciplinary approach include neuroscience education [42,43], physical activity [44,45], nutrition [46], social engagement [47,48], mindfulness [49,50,51] and other psychotherapies [52,53].

[redacted] endorses the need for further research to examine the efficacy and safety of long term opioid therapy in CNCP. There is a particular need to determine whether any sub-groups of patients experiencing CNCP have greater likelihood of ongoing therapeutic benefit and lesser likelihood of harm. Alternative research methodologies such as n-of-1 trials and benchmarking studies are required, given the impracticality of conducting randomised controlled trials over a time frame relevant to chronic pain.

PRINCIPLES OF OPIOID PRESCRIBING

[redacted] recognises that at the present time opioids are widely prescribed for CNCP despite the lack of clear evidence of efficacy. Given this reality, the following principles are offered to guide their prescription.

1. Comprehensive assessment

[redacted] strongly endorses the sociopsychobiomedical framework for assessment and management of people experiencing CNCP [54]. This is not to ignore biomedical (somatic) contributions, where a confident diagnosis should be made if possible.

Sociological assessment identifies factors in the patient's environment related to family and other relationships, work, life events, housing, sleep, activity and nutrition. A bidirectional link to the experience of pain is recognised whereby such factors can worsen pain whilst the pain can also negatively impact on each of these areas.

Psychological assessment explores the patient's beliefs, mood state, behaviours and responses that may contribute to the experience of pain and treatment outcome. Relevant beliefs include understanding of diagnosis and prognosis, and expectations about treatment, including willingness to be an active participant. As the experience of chronic pain is commonly accompanied and influenced by mood and anxiety disorders, these should be evaluated through interview or questionnaire, as an indicator for further professional input. Behavioural responses to pain can include avoidance of activities likely to aggravate pain or overdoing these same activities after taking analgesics. Cognitive impairment, personality traits and disorders should also be considered.

Comprehensive assessment also addresses the risk of opioid misuse [18,55]. In broad terms, the potential for problematic opioid use, including addiction, is higher in younger patients, those without a confident biomedical diagnosis, those in contact with users of non-prescribed medication, those with active substance abuse problems or patients with co-morbid psychiatric disorders. Such considerations need not necessarily preclude opioid therapy but act as alerts to guide close monitoring.

2. Multimodal therapy

Pharmacotherapy for the patient experiencing pain is only ever one part of a multimodal plan towards self-management [56] and should be prescribed on a time-limited basis.

Non-drug therapies include education, pacing of activity including use of the painful part, addressing postural components, structured exercise programs, sleep hygiene and psychological therapies, with input where required from nurse educator, physical therapist, psychologist, occupational therapist, social worker, rehabilitation counsellor or dietitian.

Drug therapy for patients in pain is mainly for symptom control. In some situations where the mechanism of pain can be confidently determined, such as inflammatory or neuropathic conditions, anti-inflammatory or anti-neuropathic agents respectively may be helpful in modifying pathogenesis. However in most cases, symptom control itself is important, not only for reduction in distress but also as an adjunct to non-drug therapy towards an improved quality of life.

Paracetamol has been recommended as first-line drug therapy for CNCP; however this has been challenged by a recent systematic review [57]. Non-steroidal anti-inflammatory drugs (NSAIDs) offer little advantage over paracetamol [58], especially in the most common situations when inflammation is not the relevant mechanism.

Non-opioid adjuvant analgesic agents can be considered before opioids, especially for treatment of neuropathic pain. These include tricyclic antidepressant drugs (amitriptyline, nortriptyline), serotonin-noradrenaline reuptake inhibitors (venlafaxine, desvenlafaxine, duloxetine) and anticonvulsants (gabapentin, pregabalin). Co-morbid anxiety or depression should be treated by psychological approaches and/or appropriate medications.

Invasive medical procedures (injections, implants) may be considered in selected cases to support active self-management, in parallel with the above approaches. However the evidence for long term benefit is weak and there is significant risk of harm.

3. Opioid therapy

If after comprehensive assessment, opioid therapy is thought warranted as part of a multimodal plan facilitating self-management, there are several important aspects of prescribing to consider:

i. Agreement regarding an opioid trial
ii. Conduct of an opioid trial
iii. Response to difficulty in achieving or maintaining therapeutic goals
iv. Understanding of appropriate weaning strategies

[redacted] emphasises that it is the responsibility of each prescriber to be thoroughly acquainted with not only the clinical pharmacology of the various opioids and their interactions with other drugs but also the regulatory requirements imposed by the jurisdiction in which they practise.

I. AGREEMENT REGARDING AN OPIOID TRIAL

The aim of an opioid analgesic trial is to discover the individual's responsiveness to this therapy in terms of improved quality of life. This requires frank articulation of the goals of the trial, including an agreement that if the goals are not met, then the treatment will be discontinued. The goals are beyond pain relief alone and emphasise improvement in physical, emotional and mental functioning, including an increase in activity. These goals can be negotiated according to the individual's wishes and capacity.

In this respect, a therapeutic contract is established, which can be made explicit verbally, through entries in notes or in a formal written agreement. This contract reflects the seriousness of the undertaking between prescriber and patient. There should be only one prescriber of a patient's opioids, with adequate back-up provision should that prescriber be unavailable. Ideally, the one pharmacy should dispense the opioid. Once opioid-responsiveness is established and adverse-effect profile addressed, the contract can be extended, with caveats such as no early repeats, no replacements for loss and an option for random urine monitoring (where appropriate) until a stable dose regimen is established. The contract may include an option for a time-limited maintenance period before staged withdrawal of opioid therapy.

II. CONDUCT OF AN OPIOID TRIAL (Appendix 1)

Chronic pain should not be treated with short-acting drugs (oral, transmucosal or parenteral), as the more rapid onset of effect increases the potential for positive reinforcement of drug-taking. For this reason avoidance of or weaning from short-acting preparations is suggested, in favour of a trial of long-acting or sustained-release preparations (oral or transdermal).

The use of opioid analgesics in the management of pain is an ongoing individual trial of therapy. Regular assessment addresses and documents "5As":

- Analgesia
- Activity
- Adverse effects
- Affect
- Aberrant behaviour

Titration of dose according to this "5A" assessment need not be rapid: such a trial may take several weeks. An improvement in overall well-being in the opioid-responsive patient may incur "incident" pain, which can be addressed pharmacologically by a modification of the long-acting opioid dose rather than by adding a short-acting agent. The question of a "ceiling dose" has not been settled. Caution is warranted at oral morphine equivalent daily doses (oMEDD) >40mg [20,21,59,60,61] and doses above oMEDD of 100 mg [61] should prompt reassessment and specialist advice (Appendix B). Particular caution is required in prescribing transdermal fentanyl patches, as the lowest available dose (12mcg/hr) is close to the oMEDD 40mg threshold.

Once opioid-responsiveness and stability of dose have been achieved, regular review should be undertaken, with repeat prescriptions contingent on ongoing satisfactory "5A" assessment. At least annual peer or specialist review is recommended.

III. RESPONSE TO DIFFICULTY IN ACHIEVING OR MAINTAINING THERAPEUTIC GOALS

Difficulty in achieving satisfactory "5A" assessments in the context of the individually tailored goals of an opioid trial may be attributable to pharmacodynamic, pharmacokinetic or behavioural factors. Pharmacodynamic factors, such as non-responsiveness of distress or development of intolerable adverse effects, and pharmacokinetic factors, such as insufficient (or excessive) duration of effect, may respond to change in opioid preparation or change in dosing regimen. Behavioural factors, such as poor activity pacing, may respond to specific attention to those aspects.

Variations in stability of dose and responsiveness over time, including apparent increase in dose requirements (other than for incident pain), may reflect change in the underlying biomedical (somatic) contribution, development of tolerance (pharmacological, psychological or increased sensitivity to stimuli), change in mood, social circumstances or other stressors, or development of aberrant drug-taking behaviour. Such situations require comprehensive reassessment.

Actions arising out of such re-assessment may include recalibration of goals of therapy, reconsideration of other modes of therapy, consultation with colleague(s) and opioid reduction, to the minimum effective dose or cessation.

IV. UNDERSTANDING OF APPROPRIATE WEANING STRATEGIES

A clear understanding of pragmatic exit strategies is required for any doctor prescribing opioids. The involvement of Addiction Medicine services can often be helpful in considering prescribing boundaries and therapeutic pathways. Specific weaning strategies in the context of transition to self-management include:

1. If opioids are commenced for the pain of acute nociception, there is a need to give clear direction about the anticipated duration of therapy. Typically opioids should be weaned and ceased as the acute injury heals. Even in complex cases this should be within 90 days.

2. In situations where long term opioid therapy has been maintained (at times for many years) without meaningful improvement in function, the desired outcome is weaning to cessation if possible. One practical strategy is to reduce the daily opioid dose each month by 10-25% of the starting dose. This brings cessation in 3-9 months.

3. If weaning is required after a shorter period of opioid therapy, such as after failure to achieve the goals of an opioid trial, or after a negotiated treatment phase for acute pain, then a faster rate of weaning is generally appropriate. One option is a step-wise reduction of the daily opioid dose each week by 10-25% of the starting dose.

4. If weaning is required in response to significant adverse effects or opioid misuse, then daily step-wise reduction may be more appropriate. Alternatively, immediate opioid cessation and pharmacological treatment of withdrawal symptoms can be considered.

5. If a previous attempt at opioid weaning has proven unsuccessful, then the rate can be slowed. This can be achieved by reducing the size of the dose reduction each month and/or by increasing the time spent at each dose level (eg. 2 or 3 months between reductions).

6. In some cases it may become apparent during weaning that the primary problem is opioid dependency rather than pain. If so, referral to an Addiction Medicine service is recommended.

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