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Standing Committee on Health, Ageing, Community & Social Services

Inquiry into the Exposure Draft of the Drugs of Dependence

(Cannabis Use for Medical Purposes) Amendment Bill 2014

&

Discussion paper.

Stakeholder:

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Executive Summary

In light of the increasing public debate around the use of cannabis for medicinal purposes. and the growing tide of scientific evidence supporting this plants therapeutic effects, it is an important task that this committee has been charged with...one which can have the potential to benefit and change forever the lives of patients and families right throughout this country.

Cannabis has a long history of use and is utilised in many countries around the world as a medicine for a number of clinical conditions. Now is not the time for more clinical studies; now is the time to consolidate the information we already have and make meaningful changes to patients' lives. I have witnessed patient suffering first hand and have seen the relief this plant can bring them, and encourage this committee to keep this human element in mind when working through the evidence presented before it. In conclusion, this stakeholder believes that the ACT government should fully support the legal use of medicinal cannabis as a medication for patients who can benefit from its therapeutic effect.

Stakeholder Background

Justin Sinclair is an independent consultant in the field of herbal pharmacology and phytochemistry, and established his business Traditional Medicine Consultancy in 2006. He completed a Master of Herbal Medicine with the Faculty of Pharmacy at Sydney University in 2004, which focussed on the topics of medicinal botany, pharmaceutical technology, analytical phytochemistry, toxicology and pharmacognosy. Bachelor level studies were in the field of Health Science at the University of New England.

He has held positions in the CAM industry exposing him to regulatory affairs, quality control and new product development departments. He has been in clinical practice since 2004 and has clinical interests in the areas of pain management and mental health. Current research interests include plant pharmacology for inflammation and immunomodulation, and the therapeutic applications of cannabinoids from *Cannabis sp.* He has been lecturing in biomedical, herbal medicine and clinical subjects regularly since 2003 at various educational institutions.

Mr Sinclair is a former Examiner and Executive Director of the National Herbalists Association of Australia (NHAA) and has authored several peer-reviewed publications on the topic of herb/drug interactions and pain management. He has extensive committee experience and has recently returned from a self-funded research trip investigating medical cannabis use and legislation in California, USA.

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Disclaimer

The stakeholder is currently employed contractually by the Endeavour College of Natural Health and the Australasian College of Natural Therapies (ACNT) as a lecturer in the subjects of herbal pharmacology and phytochemistry, herbal therapeutics, anatomy and physiology, clinical pathology and botany.

The stakeholder has no affiliation with any companies at this time, private or public, that stand to gain financially or otherwise from changes in legislation that may endorse or approve the use of cannabis for medicinal purposes.

The views expressed in this submission are my own, and do not represent the official views of any company or organisation that I am affiliated with.

Definitions.

Active constituents:

Substances in plant materials that are primarily responsible for the therapeutic effects; typically these constituents are secondary plant metabolites.

Botany:

A branch of Biology that focuses on the scientific study of plants, including plant structure (morphology), genetics, ecology and classification.

CAM:

Complementary and Alternative Medicine.

Phytochemistry:

A branch of Chemistry concerned with plants and plant products (i.e. active constituents).

Pharmacognosy:

A branch of Pharmacology concerned with medicinal drugs obtained from plants and other natural sources.

Pharmacology

A branch of medicine and biology concerned with the study of the effects of drugs on the human body.

Foreword.

The use, development and progression of the knowledge of medicinal plants is intrinsically interconnected with human evolution, (1) and can be traced back to the middle Palaeolithic period.(2, 3) Cannabis has been distributed by humans over the last 10,000 years throughout Central Asia, China and the north-western Himalayas, to all major temperate and tropical regions of the world.(4) It is one of the oldest psychotropic drugs known to humanity (5) and has been used in China since the Neolithic period, around 4000BC.(6) Actual written documentation of cannabis use dates back to a Chinese Pharmacopoeia written under the rule of Emperor Shen Nung dated circa 2000 BCE.(7)

From a phytochemical perspective, cannabis is incredibly chemically complex, having a myriad of active constituents imparting therapeutic benefit. More then 750 secondary metabolites (4) have been identified in various *Cannabis* species, making it one of the most phytochemically abundant plants in Nature. Phytochemicals from the cannabinoid class include the psychoactive delta-9-tetrahydrocannabinol (THC), to other cannabinoids such as cannabidiol (CBD), tetrahyrdocannabivarin (THCV), cannabigerol (CBG), Delta-8-tetrahydrocannabinol, cannabielsoin (CBE), cannabichromene (CBC) and cannabinol (CBN) (7). Cannabis also includes large numbers of therapeutic terpenoids (monoterpenoids and sequiterpenoids) as well as flavonoids, fatty acids, amino acids and coumarins. (4)

And in recent times, after 10 millennia of medical use, cannabis has now been effectively made illegal to possess, sell or grow. Considering that in 1936 it was still listed in the United States Pharmacopoeia for numerous therapeutic applications, and now it is a Schedule 1 drug under the Controlled Substances Act (7) in that same country, we must question why this has happened. When one reviews the enormous amount of scientific, toxicological and pharmacological literature amassed on this plant over the last 100 years of research, it is time for governments around the world to consolidate this research and return this plant to those that need it – the terminally ill, the chronically sick and those in constant pain.

This is not the story of a ‘coming of age’ of this medicinal plant...nor is it experiencing a renaissance, as when viewed with associated evidence and historical use, we could rightly argue it is has been an ‘age in coming’ and a rightful return to its place in the human story as a medicine for all mankind.

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1. Are the recognised illnesses and conditions appropriate?

Category 1 clearly identifies the use of cannabis in terminal illness, and what denotes a terminal illness (Projected death in less then 12 months). This application requires the patient's doctor to declare that the patient has *tried or considered* all conventional treatments for the symptoms of the illness or its treatment. Personally, the stakeholder feels the term '*doctor'* needs to be modified in this section to "*specialist medical practitioner*" or "*specialist doctor*", as for a patient in this particular clinical position it would be expected that they be under the care of a specialist medical practitioner, not a general practitioner. Furthermore, the title *doctor* is not a protected title and can include professional and research doctorates in fields unrelated to medicine. The term *medical practitioner* is a protected title in Australia and is perhaps more appropriate in this particular piece of legislation.

Furthermore, based on the seriousness of Category 1 applications, it should be considered that these applications would take priority over other category applications when being reviewed by the Chief Health Officer (CHO) due to time constraints and the seriousness of the disease.

The question is also raised at this point as to whether new or experimental drugs (i.e. those not yet approved for use for a specific condition by the TGA) constitute *conventional treatment* based on the wording of this particular segment of the discussion paper. The stakeholder does not believe that a patient should be made to trial an experimental drug before being able to try medical cannabis for disease management or symptom relief.

Category 2 applications are focused on serious diseases and conditions such as cancer, AIDS, HIV, spinal cord injury or disease, multiple sclerosis and epilepsy. This expands to also include specific symptoms such as severe nausea for cancer and seizures for epilepsy. This stakeholder is in complete agreeance that the legislation is written in such a way as to include further diseases / conditions / symptoms to be added by regulation at a later time if the need arises, as other conditions such as Systemic Lupus Erythematosus (SLE), rheumatoid arthritis, chronic neuropathic pain (5, 8, 9), inflammatory bowel diseases (e.g. Crohn's Disease) and fibromyalgia have shown promising treatment outcomes in case study and other evidence based literature.

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Under the proposed legislation for **Category 3** applications, chronic but less serious conditions such as glaucoma are mentioned. The stakeholder counsels that Crohn's disease, and more advanced Parkinson's disease, as general examples, are perhaps more appropriate as category 2 applications.

In summary, the discussion papers proposed legislation does provide a sound and modifiable platform to accommodate for a variety of medical conditions and seems both sustainable and equitable.

2. Are the requirements for medical involvement in the applications process appropriate and adequate?

Due to the nature of the diseases being treated in all application categories, and the need for medical investigations or imaging that must occur to facilitate both the original diagnosis and management of these diseases and conditions, it is completely appropriate that registered medical practitioners manage this.

Conversely, one could question whether medical practitioners could bias or hinder the ability of patients to access medical cannabis due to their lack of training in the endocannabinoid (EC) system or familiarity with the phytochemical constituents in cannabis, or what conditions they can be used to treat. This has been discussed in more detail, with a potential solution, in **Addendum 1.2**.

It is the opinion of this stakeholder that based on the current training and general lack of knowledge on cannabinoid based phytomedicines, medical practitioners in Australia are currently ill qualified to be a source of detailed knowledge on this topic for patients seeking medical cannabis. Courses specifically designed to train medical practitioners in this area of practice, and the various cannabis strains useful for medical conditions, should be essential as part of the ongoing roll out of this legislation.

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3. Is it sufficient that for Category 2 and Category 3 applicants all regular treatments are "Medically inappropriate"? Should other factors be relevant – for example, if a treatment is unaffordable?

The discussion paper for Categories 2 and 3 stipulates that the patient has tried or considered all conventional treatments for the symptoms of the illness or its treatment, and each of them is medically inappropriate, as deemed by a medical practitioner. The stakeholder would also consider that the cost of medication be considered here, particularly for elderly patients or other people who are socioeconomically disadvantaged. This should be appropriate as a justification to not try all medical treatments.

Another potential obstacle that has not been raised here is the religious or cultural background of the patient and how this may impact on conventional treatment options (e.g. blood transfusions, exposure to ethanol etc.) and the emotional and spiritual wellbeing of the patient.

4. Does the legislation strike the right balance in regards to eligibility for children to use medical cannabis?

This stakeholder does not possess expertise within the field of paediatrics, so cannot comment on this from a knowledgeable position. Notwithstanding, it seems appropriate that a committee could be formed to investigate the actual impact of various cannabinoids on the developing brain in children, as many of the over 60 cannabinoids do not exert any psychoactive effect whatsoever, such as cannabidiol for example, thus potentially reducing the likelihood of long-term adverse effects.

Given the Category 3 descriptor, it seems appropriate that the CHO can make this decision for rejection of child applications, but perhaps a clause can be included for special circumstances? This could potentially be submitted to the CHO by the child's specialist medical practitioner on the grounds of disease progression, adverse effects or conventional treatment failure. This seems suitable considering the medical practitioner would have first hand medical knowledge of the case, know all of the patient history and have the child's best interests in mind.

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5. Are the conditions for permits to use cannabis sufficient and appropriate?

This stakeholder recently returned from California (USA) on a self-funded research trip investigating medicinal cannabis use and current state legislation. Californian Proposition 215, also known as the *Compassionate Use Act of 1996*, allows for the possession and cultivation of cannabis for personal medical use and has since been expanded to allow for collective and cooperative growing distribution for medical purposes. In accordance with this legislation, photo identification in the form of a *Medical Cannabis Card* is issued to successful applicants, which must be shown to purchase medical grade cannabis from dispensaries. It is also for identification to law enforcement officers and is completely appropriate for such legislation as outlined in the discussion paper. It also allows for future integration if legislation is passed for government endorsed medical growing facilities that can produce high quality, phytochemically varied cannabis species for numerous conditions and diseases.

The specification that the permit to use cannabis can only be valid for a 1 year period before renewal seems cumbersome considering some patients will have diseases or conditions that are lifelong and thus requiring long term treatment. As such, perhaps allowing longer renewal times of up to 2-3 years is appropriate for certain conditions (to be pre-determined) as long as the patient is receiving regular (minimum twice yearly) follow-ups with their respective specialist medical practitioner?

This section of the discussion paper also stipulates that the CHO is to set the maximum quantity of cannabis the person may possess at any time. This is certainly appropriate, but does not specify if this is dried or fresh weight of cannabis inflorescence, nor does it cover if the patient has decided to manufacture that cannabis into other useable dosage forms such as oils, tinctures or other ingestible substances. This may need to be considered when it comes to establishing amounts of cannabis (dried herb equivalent), and could be potentially calculated based on weight to volume ratios and / or quantitation by input.

Furthermore, this leads to the discussion on whether applicants must be *residents* of the ACT to apply for medical cannabis use? Based on current

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estimates, it appears fair to say that the first state or territory to legislate medical cannabis will see an influx of patients, carers and families moving there to gain access, so this discussion is important at this early developmental stage. This influx of potential patients could put a considerable burden on the territory CHO and cannabis approval process, slowing down access if appropriate steps are not put in place. It is the stakeholders belief that anyone fulfilling the criteria for application to Category 1, 2 or 3 should not be denied access due to coming from a different state or territory should they wish to now reside in the ACT for medical purposes.

6. Are the conditions for permits to cultivate cannabis sufficient and appropriate?

The guidelines raised in the discussion paper in relation to the cultivation of medical cannabis seem appropriate and allow for CHO discretion based on individual patient requirements. The defined amount not exceeding trafficable amounts of 300g is appropriate and allows for patients to have access to substantial amounts of cannabis to address symptomatology. Previous criminal conviction of drug offences precluding people from participating in the cultivation of cannabis is responsible and well considered.

What is not made particularly clear in the discussion paper is whether cultivation includes indoor (inclusive of hydroponics) or outdoor growing of medical cannabis, or allows for both. The paper alludes to requiring the address of the place of cultivation and security steps needing to be taken to stop potential theft of the cannabis, but does not elaborate on whether possession of growing equipment etc. is also covered by legislation as being permissible.

The paper discusses that a limit of 10 plants would be placed on each patient / cultivator as an upper limit per application. Should the patient be using the leaf specifically for obtaining certain phytochemicals, and juicing these leaves daily, they will quickly exhaust a crop of 10 plants, as the leaves are how the plant provides food for itself through photosynthesis and stripping them too often will cause the plant to die off and also reduce secondary plant metabolite manufacture. Recommendations in this instance would be to allow a larger crop number for those that juice the leaf daily. In discussion with various patients that do so in the USA, they maintain that 15-20 plants allows them to

do so without causing significant plant stress. Please understand that these patients did not use the inflorescence (flowers / buds) for medicinal purposes.

Perhaps most importantly, and concerning to this stakeholder, is the complexity and experience needed to grow high quality medical cannabis. The paper does not seem to cover where patients can get access to good seed stock to grow medicine that they may be needing now, not in 3-6 months after a growing cycle. In essence, the paper implies that they would need to get this seed from essentially criminal elements.

Factors such as irrigation, soil pH, seed and clone selection, sexing of plants, humidity and moisture, air circulation, temperature control, altitude and light cycles (4) all come into play to growing a good quality cannabis crop with high enough levels of phytochemicals to be considered therapeutically useful. While this legislation in its current form is absolutely critical as a starting point for people to gain access to medical cannabis in the first instance, it hasn't empowered these same people with the tools to do so with confidence or with species that could maximise the therapeutic outcomes and management of their conditions.

Also worthy of consideration is the fact that cannabis can be prone to a host of bacteria, fungi and pests associated with both indoor and outdoor cultivation.(4) Spider mites and aphids are of concern, and pesticide usage may reduce quality of the final product, or also increase risk of harm depending on the chemicals used and the method of final use by the patient (e.g. inhaled etc). Fertiliser selection is also important, as outbreaks of hepatitis have been reported in Mexico and Germany from using human excrement.(4, 10) Heavy metal exposure, pesticide limits and microbial and fungal limits will not be able to be assessed, showing further support for a push towards government endorsed medicinal cannabis growing facilities to ensure patient safety and reproducible phytochemistry which allows for consistent therapeutic outcomes.

7. Is three (3) years an appropriate period before the review occurs?

The timeframe for review as proposed by the discussion paper is appropriate and the description of how the review will take place is well considered.

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8. How should drug-driving laws deal with the issue of legalised medical cannabis?

As cannabis can be a psychoactive substance and alter a person's ability to safely operate heavy machinery or drive a vehicle, it is completely appropriate that patients using medical cannabis follow and abide by state or territory drug-driving laws. Cannabis can be detected in the body of users via drug testing methods / assay for long periods of time after original ingestion or usage. Until more sophisticated and sensitive technology exists to determine what is an acceptable limit allowable in the blood or body tissues, users should do their best to avoid driving for their own safety and the safety of others when consuming daily amounts of medical cannabis, particularly of high THC concentration.

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1. Addendum – Additional commentary & feedback.

1.1 Inclusion of different species.

On page 2 of the "Medicinal Cannabis discussion paper" it gives mention specifically to *Cannabis sativa* in the context that this is the only botanical species of potentially therapeutic cannabis. The stakeholder wishes to advise that *Cannabis indica* is also a very therapeutic / medicinal species that deserves inclusion within the paper. *Cannabis ruderalis* is also another species that may be worthy of inclusion due to its ability to undertake autoflowering (therefore being potentially easier to grow and with shorter times before harvest). Whilst producing lower delta-9-tetrahydrocannabinol concentration, certain authors suggest it can have higher cannabidiol levels, which is of great value in the medical cannabis community.

1.2 Training for medical practitioners

Page three of the Discussion paper discusses the need of a medical declaration whereby a medical practitioner agrees to the use of cannabis for a particular illness or pain. It also goes on to explain that the medical practitioner would discuss the likely risks and benefits of using cannabis. This concerns the stakeholder for two reasons –

1.2.1 – Medical practitioners have very little working understanding, knowledge or education in the Endocannabinoid system (ECS). Cannabinoid 1 (CB_1) and Cannabinoid 2 (CB_2) receptors are distributed throughout many parts of the body. CB_1 receptors are those that mediate the psychoactive effects of the cannabis plant and are more closely associated with the central nervous system, with highest binding in the basal ganglia, substantia nigra and cerebellum. (7) Conversely, CB_2 receptors are more closely linked with cells in the immune system. Both cannabinoid receptors are G-protein coupled receptors. Recent research is starting to understand the normalising effect this system can have on achieving and maintaining homeostasis within the body.

The stakeholder's viewpoint is also in line with the findings of the NSW report on the use of cannabis for medical purposes (report 27), which stated:

"cannabis based treatments will only be appropriate for a small number of people in specific circumstances, and under the supervision of medical practitioners with ***suitable expertise****".* (11)

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It is critical that medical practitioners working with this plant receive the appropriate training required to maximise therapeutic outcomes for potential patients.

1.2.2 – Medical practitioners have very little understanding of the different physiological effects of cannabis based on the active constituents or ratios of active constituents the plant material possesses. This plant is not a single active constituent pharmaceutical agent that can utilise altered dosing regimes to change therapeutic outcomes...it is the differing levels of various constituents, and the synergistic effect they have, that produces an overall pharmacological action (the entourage effect), so represents a significantly different paradigm to what modern medical practitioners are used to in the current orthodox model.

Solution – The stakeholder advises that a committee of independent experts in the fields of medicine, anatomy, physiology, neurobiology, pharmacology, pharmacognosy, toxicology, medical botany and horticulture be established to design and write a course for medical practitioners educating them on both the role of the endocannabinoid system in human health, and also the different types of phytochemically useful cannabinoids. Examples of medicinal strains of cannabis can also be investigated that can be recommended to patients suffering various pathology, making the course clinically applicable. Methods of cannabis administration and associated health problems can also be examined. This course should, in theory, be completed by any medical practitioner who could potentially be assessing patient suitability for medical cannabis.

1.3 Quality control / Quality assurance of Medical Cannabis

Whilst this legislation is a great step forward to empowering the terminally sick and chronically ill in taking steps to improve their quality of life, the legislation does not look at providing a very important aspect of medicinal cannabis – chemical quality. The chemical complexity of various species and strains of Cannabis is well beyond the scope of understanding of many people that are simply in need of it for chronic pain or terminal illness

Whilst the terms ‘medical cannabis’ or ‘medicinal cannabis’ denotes a species of cannabis that can be used to manage or treat ‘medical’ conditions, it also implies that cannabis can be of a medical “grade” or “quality” to achieve said ends, therefore setting up such a system as currently stands but not

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addressing the supply of quality medicinal species / strains will reduce the efficacy and therapeutic potential of the legislation to end users.

This is in line with guidance from Mather who states that:

"*Whereas most recent studies of medicinal cannabis involve medicinal-grade cannabis in institutionally approved trials, studies of recreational cannabis are largely based on street grade cannabis in unknown circumstances, and are therefore of questionable value for either explicit pharmacology or extrapolation to patients undergoing cannabis pharmacotherapy".*(12)

Conclusion.

This stakeholder applauds the move to legislate medicinal cannabis in the ACT and feels that the provided framework in the form of the discussion paper is a good working platform to base this on.

Far more important at this time then spending valuable tax payers dollars on clinical trials is the necessity to enact laws that can reduce or stop human suffering. It is my opinion that a think tank could be set up, pulling from countries and experts all over the world, to address the issue of medicinal cannabis and learn from the mistakes of others. This would be far more valuable then trials that even if conducted well and showing clinical or statistical significance, will only benefit a chosen few.

I wish the committee well in its review process and offer any assistance that I can provide to further this important legislation.

Sincerely,

Justin Sinclair.

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