MEDICINAL CANNABIS

A SUBMISSION IN RESPONSE TO: VLRC ISSUES PAPER MARCH 2015

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A working group of the Cannabis Community of Victoria.

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I would like to thank the Victorian Law Reform Commission ("VLRC") for the opportunity to make this submission.

There is presently no formal association operating within Victoria that represents the views of the Cannabis Community of Victoria ("CCV"). Accordingly, this submission was requested and prepared with the assistance of Mr Fred Adnronikis together with contributions made by a small working group of individuals from within the Cannabis Community of Victoria ("CCV"). Further contributions and assistance were also received from many other sources including:

- Mr Paul Armentano of NORML in the USA;
- Ms Mara Gordon and founder of Aunt Zelda's, USA;
- Mr Marcel Gignac of the Medicinal Cannabis Patients Alliance of Canada Inc;
- The British Columbia Compassion Club Society, Vancouver, British Columbia, Canada;
- Mr John Conroy Q.C, Constitutional and Human Rights Lawyer, Canada;
- Mr Ian Breakspear, Australian Clinical Herbalist, Naturopath, Lecturer and Author;
- Emeritus Professor, David Pennington, AC.

Mr Adrian Columb is to be acknowledged for his tireless contributions and editorial assistance.

I trust that the content of this submission will be beneficial to the VLRC in the discharge of it's responsibilities in advising the Victorian Government on the operation of a Medicinal Cannabis Scheme in Victoria.

DISCLAIMER:

The information in this submission is presented for general information purposes only. The author has attempted to present the material to the best of her ability but makes no representations or warranties generally or otherwise, including but not limited to: the accuracy of the submissions content and or any materials relied upon and cited within it. The content of the submission is for education and information purposes and is not intended and should not be relied upon as advice in any capacity whether legal, medical or otherwise. Persons reading this submission should seek professional advice on any information presented therein and are reminded that cannabis possession and use is a scheduled poison and a substance prohibited by law attracting criminal prosecution.

PART ONE

TERMS OF REFERENCE

The Cannabis Community of Victoria (''CCV") acknowledges that:

1. The Victorian Government is committed to enabling Victorians to have lawful access to and use of cannabis for medicinal purposes in ''exceptional circumstances.''

2. On the 19th December, 2014 under S. 5(1)(a) of the Victorian Law Reform Commission Act 2000 (Vic) the Victorian Attorney General, the Hon. Martin Pakula, M.P., requested the Victorian Law Reform Commission ("VLRC" or ''the Commission'') to review and report on changes to Victorian laws that would achieve this outcome.

3. The terms of reference provided to the Commission were:

   (a) to review and report on options for changes to the Drug Poisons and Controlled Substances Act 1981 (Vic) and associated regulations which would allow people to be treated with medicinal cannabis in ''exceptional circumstances.''

   (b) to make recommendations for amendments (if any) to the:

   - Therapeutic Goods (Victoria) Act 2010
   - any other relevant legislation.

   (c) In conducting the review the Commission has been asked to consider:

   - the operation of the laws referred to and how they interact with Commonwealth law, functions and any relevant international Conventions;

   - medicinal use of cannabis in other jurisdictions.

   (d) The Commission is asked to appoint expert panels to assist in its review to examine specifically:

   - prescribing practices, including eligibility criteria for access to medicinal cannabis and the role of doctors in managing its use by patients;

   - regulating manufacture and distribution, including the forms of medicinal cannabis that should be permitted for use.

4. The Commission has established two advisory committees to comply with the terms of reference set out at 3 (d):

   (a) a medical advisory committee of experts in the therapeutic use of cannabis and current clinical research.

   (b) a regulatory advisory committee of experts in effective regulation and the

operation of current law and overseas reforms.

5. The terms of reference do not invite the Commission's views on this matter or on whether the prohibition on cultivation, production, supply and or use of cannabis should be fully removed. The Commission makes no comment on these matters.

6. On the 17th March 2015 the Commission issued a discussion paper: "Medicinal cannabis – Issues Paper'' (''issues paper''). This publication provides background information and raises questions identified as issues for further consideration. The publication of the paper, marks the beginning of the consultation process between the VLRC, stakeholders and the general community referred to as ''interested parties."

7. The Commission is seeking written submissions from interested parties on the issue paper, terms of reference and/or anything arising out of such, to be received by 20th April, 2015, with follow up discussion to identify law reform options thereafter.

8. The Cannabis Community of Victoria ("CCV") is a major stakeholder in this process. It desires and anticipates engaging with the VLRC, State Government and other relevant stakeholders in the formulation of a medicinal cannabis scheme for Victoria.

9. The Commission proceeds on the basis that the review undertaken should be evidence based, open and balanced.

THE CANNABIS COMMUNITY OF VICTORIA

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The Cannabis Community of Victoria, or ''CCV'' has a long history. Cannabis arrived in Australia on the First Fleet at the request of Sir Joseph Banks in 1788[1] Consumption became widespread in the Victorian colony, and it was heavily used in the 19th and 20th centuries.[2] Marcus Clarke, well known Melbourne based journalist and celebrated Australian novelist and poet, wrote on cannabis use in Victoria during the 19th century, including a short story entitled: "Cannabis Indica'' allegedly penned whilst consuming cannabis.[3] Members of Melbourne's Bohemian Yorick Club (circa 1860 and the forerunner to Melbourne's Savage Club) established for those with a professional interest in literature, visual arts and science, were reportedly notorious cannabis users.[4] Cannabis was also a popular over the counter medicinal at this time, which was available in Australia in various preparations up until 1938 and in some reports until the 1960s.[5]

Since the introduction of the laws of prohibition surrounding cannabis use and possession the Cannabis Community of Victoria ("CCV') has lobbied continuously and tirelessly for their abolition and has remained defiant in continuing to cultivate, use and compassionately provide medicinal cannabis for those in need of the healing properties of this plant.

The CCV maintains the view that the inclusion of the plant as a narcotic and its scheduling as a controlled and prohibited substance in successive UN Conventions was not only factually incorrect, but took place without the presentation of any formal evidence to support the contention that it was a dangerous drug or one as dangerous as opium.[6] Sixty years hence, science has validated what the CCV has known all along: that when used responsibly cannabis is a safe and effective food, recreational, medicinal and spiritual herb.

Today, the CCV comprises of a diverse range of individuals, as well as a state branch of a long standing political party: The HEMP Party (Victoria).

The HEMP (Help End Marijuana Prohibition) party of Victoria is a political party formed with the sole intent of bringing an end to the current laws of prohibition surrounding access to and the use of the cannabis plant.

The objectives of the HEMP political party include legalising cannabis in all states and territories in Australia for personal, medicinal and industrial purposes.

Whilst not all those participating in the CCV are members of the HEMP party, the community and the HEMP party are closely affiliated and aligned. This submission is however, independent of and separate to, any submission made by the HEMP party.

Individuals within the CCV vary in age, ethnicity, religious practices and socio/economic background.

The community currently includes:

- short and long term illicit consumers of cannabis and cannabis products for health, well being, medicinal and/or spiritual purposes;
- persons who have never consumed cannabis or cannabis products but desire to do so lawfully for health, well being, medicinal and/or spiritual purposes;
- short and long term illicit consumers of internal digested hemp seed and hemp seed products;
- persons who have never internally consumed hemp seed and/or hemp seed products, but desire to do so lawfully for general health and wellbeing;
- persons who are currently or wish to become licensed cultivators, manufacturers, and/or distributors of industrial hemp and associated products;
- persons who are currently cultivating, manufacturing and or distributing cannabis to those who require it for recreation, general health, medicinal and/or spiritual purposes;
- persons who have never cultivated, manufactured and/or distributed cannabis for recreational, general health, medicinal and or spiritual purposes, and wish to do so lawfully;
- professional persons including but not limited to doctors, nurses, allied healthcare professionals, scientists and lawyers who recognise the scientific merits of hemp and cannabis for general health, and who advocate for its lawful use and the need for further research.

Interest in and the size of the community has expanded in recent years. This is not surprising considering that:

- cannabis is the most commonly used illicit substance both in Australia and worldwide[7], with 15% of the worlds users in Oceania (including Australia and New Zealand), according to the United Nations;[8]
- cannabis is the most commonly used illicit substance in Australia with 35% of persons over the age of 14 years using it over the course of their lifetime;[9]
- over 750,000 Australians use cannabis every week[10] with less than half of those persons smoking it;.[11]
- a marked increase in use in Australian adults over 50 years of age has been reported in recent times;[12]
- an increased awareness of anecdotal and scientific findings on the health benefits associated with cannabis consumption, with particular breakthroughs in relation to benefits associated with the primary cannabiniod THC and to a lesser extent CBD. There are over 20,000 published scientific studies or reviews in scientific literature on cannabis and its properties, half of which were published in the last 5 years according to a keyword search undertaken at the US government online repository for peer reviewed scientific research: PubMed;[13]
- an increase in demand for knowledge concerning the medicinal use of cannabis and access to it by the ill and their carers. The demand has been driven by a diverse number of factors.[14] The Medicinal Cannabis Users Association of Australia[15] is currently attracting over 150 new participants each week.

The CCV acknowledges and stands for the following:

Cannabis:

1. is a scientifically and historically recognized herbal botanical, food and medicine;
2. is responsive to and required by the human endocannabinoid system in the human body to maintain homeostasis: the natural equilibrium in the body that is necessary for health and wellbeing;
3. in the form of whole raw GMO-free botanical plant is promoted for good health and therapeutic use due to the "entourage effect" which involves properties in the whole plant working synergistically together to produce optimal results as intended by nature;
4. has demonstrated general health, therapeutic properties and safe uses as supported by historical medical use, international scientific patents, research studies and reports;
5. the distinction between medicinal and recreational use of cannabis is artificial as its consumption is a nutritious food and medicine that supports the general health of the human body irrespective of the intent associated with its consumption.

The Law and Human Rights.

1. The United Nations Single Convention on Narcotic Drugs (1961) recognizes the medicinal use of cannabis;.[16]
2. The United Nations Single Convention on Narcotic Drugs (1961) recognizes medicinal use of cannabis as “indispensable” for relief of pain and/or suffering;[17]
3. The United Nations Single Convention on Narcotic Drugs (1961) states that adequate provision of cannabis must be made available for medical purposes and to relieve pain and suffering;[18]
4. The laws of prohibition (International Conventions[19] together with state and federal laws based upon them which deem cannabis a dangerous narcotic, controlled and prohibited substance) are not based on fact or scientific evidence.[20] Science and individuals within the CCV today refute and challenge the inclusion of cannabis as a scheduled substance under these international, federal and state laws;
5. Cannabis is not-lethally toxic.[21] Current scheduling of cannabis in Australia under federal and or state laws and any and all references to the cannabis plant as a ‘’poison’’ whether as a medicinal or not, are false and misleading and have, and continue to, create harm;
6. Australian and international laws that classifying cannabis as a prohibited and/or controlled substance require immediate repeal and amendment. Prohibition and accompanying legal processes, including criminal sanctions must be extinguished from the statutes in their entirety;
7. The "War on Drugs" is an internationally acknowledged failure, destroying lives, community cohesion and wasting important economic and human resources.
8. Human Rights contained in the following Conventions and associated protocols:

   The Geneva Convention
   The Universal Declaration of Human Rights
   The International Covenant on Civil and Political Rights (ICCPR)
   The International Covenant on Economic Social and Cultural Rights (ICESCR)

The Convention on the Rights of the Child (CRC)
The Convention Against Torture (CAT)

The Convention on the Elimination of All Forms of Racial Discrimination (CERD),
The Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)
The Convention on the Rights of Persons with Disabilities (CRPD).
The Charter of Human Rights and Responsibilities Act (2006) Vic.

9. All human beings regardless of age, gender, ethnicity, religion, social status, standard of living or financial means should:

a. have the right of lawful access to whole raw GMO-free botanical cannabis that is a food and has health, therapeutic, recreational and spiritual value;

b. have the lawful right to possess, use, manufacture, administer, cultivate, supply and sell whole raw GMO-free botanical cannabis for the purposes identified at paragraph 1;

c. have the right to access whole raw GMO-free botanical cannabis, cannabis products and associated therapies, employed for good health and or medicinal purposes, to be supervised by a medical doctor and/ or an allied health care professional where so desired. Such health care practitioners should also have the right to recommend, advise, prescribe, treat, possess, manufacture, administer, supply and/or oversee their patients use of whole raw GMO-free botanical cannabis in accordance with their ethical standards, guidelines and the rules of sound clinical medical care;

d. have the right to have lawful access to, possess, use, manufacture, administer, cultivate, supply and sell whole raw GMO-free botanical cannabis, cannabis products and or therapies without living in fear and/or being subject to any legal process including but not limited to those that may involve criminal prosecutions and/or sanctions. Patients, their care providers, healthcare practitioners and compassionate cannabis therapists and/or providers, should not be forced to choose between intrinsic human rights. A Patients' right to health or life should never be at the potential loss of such parties right to liberty;

e. have the rights referred free from discrimination;

f. maintain unalienable rights over their own bodies. This right includes the right to determine what substances are consumed or applied, for health or general purposes. This right exists independently of what science may or may not advocate as appropriate;

g. have the right and option to grow whole raw GMO-free botanical cannabis for their own personal consumption and use. Such a right should not be unreasonably confined and or fettered by operation of law or otherwise.

THE NEED FOR A MEDICINAL CANNABIS SCHEME IN VICTORIA

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1. Cannabis is the most illicitly used substance in Australia. 35% of persons over the age of 14 years use it in Australia over the course of their lifetime.[22] It is believed that 1.9 million Australians use cannabis regularly.

2. Incidence of regular cannabis use increases with age.[23]

3. 16% of Australians over the age of 30 use cannabis daily. However, a marked increase in daily users has been noted in adults over 50 years of age.[24] Recent findings conclude that older Australians consume cannabis more regularly than younger Australians, using it more than once a week.[25]

4. This trend may be associated with an ageing population. This is supported by a recent finding that the key reasons Australians take cannabis, because ''they want to feel better.''[26]

5. This study was not on medicinal use. Consequently the comment suggests that a distinction between medicinal and recreational use of cannabis is arbitrary and artificial, as all use of cannabis provides therapeutic benefits, irrespective of the user's intent. Relaxation and stress relief are legitimate therapeutic needs. Whilst Australians use alcohol for such purposes, they are denied access to cannabis, which on balance has been shown to be a much safer alternative.

6. This point is clearly evident in the findings of the Victorian Coroner Audrey Jamieson who reported at the International Medicine in Addiction Conference in March 2015,[27] that prescription drugs involved in 82% of the 384 overdose deaths investigated by the Victorian coroner's court in 2014, were drugs commonly used to address stress, anxiety and sleep disorders. Benzodiazepines, were the most commonly implicated drug, followed by opioids, anti-depressants and anti-psychotics. Further, the deaths attributed to these prescription drugs were almost double the number of deaths involved in illicit drug use despite the widespread use of both. Professor Nicholas Lintzeris, director of drug and alcohol services at South Eastern Sydney local health district, reported that their widespread abuse meant that the harms they cause were only second to alcohol and were ''significantly greater than harm caused by illicit drugs.''[28] In fact, accidental deaths from prescription medications and in particular opioids, is more common in Australia today, than death associated to heroin use.[29]

7. It is therefore hardly surprising to learn of the recent findings of a large study by the National Drug and Alcohol Centre published in December 2014, involving 1500 Australians suffering from chronic pain associated with migraine, back pain, arthritis and similar conditions. This study found that patients aged 40-50 years, were choosing cannabis despite having been prescribed opioids. In doing so, the patients reported finding greater symptom relief from cannabis than from the highly addictive and dangerous Conventional opioid medications. It was found that these patients had been living with pain for long periods and turned to cannabis because their pain was so severe that it was interfering with the quality of their lives.[30] These are the patients that the UN Single Convention on Narcotic Drugs 1961 had in mind, when it referenced cannabis as being ''indispensable'' to the relief of pain and suffering and that adequate provision of cannabis must be made available for such purposes.

8. These findings were also consistent with those reported in a study in the United Kingdom on medicinal cannabis use, which found that 68% of medicinal cannabis users reported that cannabis made their symptoms much better overall, with 45% stating that cannabis worked much better than prescribed medications, and 34% reporting that the side effects of prescribed medications were much worse.[31]

9. Given the laws of prohibition, there are limited Australian studies and statistics on the demand for cannabis for medicinal purposes.

10. Consequently, of the 750,000 Australians currently using cannabis weekly,[32] it is unknown what percentage are doing so for medicinal purposes or to ''feel better'' and what forms of cannabis they are taking to achieve this outcome. However, we do know that of the 750,000 plus Australians using cannabis every week, less than half of that number choose to smoke it.[33] This suggests that there is a large percentage of Australians using concentrated extracts and other forms of cannabis associated with medicinal uses such as edibles and infusions (tinctures) .

11. A study[34] on medicinal cannabis users in the USA, UK and the EU reported that medicinal cannabis users turned to cannabis for treatment did so for pain (67%), with 15% using it for neuralgia and neuropathies, 18% for muscle spasms or spasticity, 11% for migraine, 11% back problems, 11% for arthritic pain, with 8% for other specific forms of pain. The second most common ailment after pain that cannabis was sought for was for insomnia (25%), followed thereafter by anxiety (22%), depression (16%), stress (10%), and post traumatic stress disorder or PTSD (10%). Gastrointestinal conditions such as nausea (9%), irritable bowel disorders (8%), and appetite stimulation (6%) were conditions also driving medicinal cannabis use, together with central nervous system disorders, which included multiple sclerosis or MS (4%) and epilepsy or seizures. Over 80% of the patients reported that cannabis was more advantageous than other therapeutic agents or treatments.

12. This study[35] also reported that the mode of administration of cannabis preferred over all others, was smoking (67%), with 47% of patients preferring an Indica or Indica-predominant strain, with a further 40 % reporting a preference for a Sativa or Sativa-rich strains. 15% of these patients also reported their observations that Sativa was considered energising, anti-depressive, uplifting, useful for exhaustion or fatigue and preferred for day time use for these reasons. Indica was considered useful for pain, insomnia, lack of appetite and was associated with night time use but was uplifting, anti-depressive, energizing, useful for fatigue or exhaustion and better for daytime use, while Indica was said to be useful for pain, lack of appetite, insomnia, and generally for night time use, but hindered day time functionality. Further, 80% of patients reported a preference for THC strains and 44% also selecting strains for their terpene content.

13. An Australian study on long term and regular medicinal cannabis use in 128 patients, with a median age was 45 years, reported similar findings. Medicinal use of cannabis in Australia was being used in 57% of patients for chronic pain, 56% for depression, 35% for arthritis, 27% for nausea and 26% for weight loss. 85% reported that cannabis gave "great relief" overall and substantial relief in relation to symptoms such as pain, nausea and insomnia. Patients also reported that it was superior to other medications in terms of the extent of relief provided and undesirable effects from other medications.[36]

14. In addition to the conditions referred to in the previous study, medicinal cannabis is sought and has been effective in a wide range of conditions. It is therefore not surprising to individuals within the CCV to note general public community support for the abolition of the laws of prohibition and the legalisation of medicinal cannabis and the support for the same, which has been growing steadily over the last 10 years. Support for clinical trials using cannabis for people with medical conditions: 73.5% (2004) 73.6% (2007), 74% (2010), 75% (2013) and support of legislative change permitting cannabis use for medical purposes: 67.5% (2004) 68.7% (2007), 68.8% (2010), 69.0% 2013: National Drug Household Survey.[37] Recent polls show that 2/3rds of Australians support legalisation of cannabis for medicinal use with highest support from 50-65 year olds,[38] with some

demonstrating that 97% of the Australian public support lawful access to medicinal cannabis.[39]

15. In June 2014, in response to Dan Haslam's campaign for the lawful access to medicinal cannabis in NSW, the Medicinal Cannabis Users Association of Australia formed on a social media platform. This group has attracted over 6,500 persons, growing at the rate of around 150 new supporters each week. A number of other Australian cannabis educational and advocacy groups have reported similar developments.

16. With increasing awareness in the community on the therapeutic application of cannabis, demand for cannabis generally is high and a sizeable black market exists to meet the demand.[40] On the basis of the aforementioned it is safe to say, so too is the demand for medicinal cannabis. In fact, there have been reports of increasing pressure on cultivators who supply the recreational market, to divert supply to the medicinal cannabis market.

17. A marked increase in demand for both knowledge on and access to cannabis for medicinal purposes has been noted. Factors driving demand for medicinal cannabis include:

    a. a desire for a natural botanical non-pharmaceutical grade product;

    b. an inability to take pharmaceutical products (i.e. sensitivity, contra Indications, adverse drug reactions);

    c. inability to access suitable pharmaceutical products, treatments or clinical trials due to:

        - high expense;
        - general regulatory barriers (cumbersome and time consuming);
        - general exclusion from clinical trials;
        - rare medical conditions without treatments and or cures; and
        - unavailability of pharmaceutical products (not approved for use by TGA in Australia).

    d. ineffective, inadequate or poor treatment outcomes/responses to pharmaceutical products;

    e. the need for time critical access to therapeutic options and responses (terminal patients and those with chronic pain or diminished quality of life through other forms of suffering);

    f. increased community awareness on the scientific findings of the nutritional, medicinal or general therapeutic value and effectiveness associated with the plant, with medical sciences inability to keep pace effectively and efficiently to community needs and demand for therapeutic solutions;

    g. a loss of faith in mainstream medicine and medical research in general due to:

        - its expensive, cumbersome, slow, over cautious, political and tightly controlled monopolies (general practice of medicine) and oligopolies (pharmaceutical companies);
        - patriarchal and commercial third line forcing approaches to patient's health, which encroach upon a consumer's right to self determination with respect to health choices.

- Contradictory medical research outcomes, medical bias, conflicts of interest in research, selective promotion of research based on ''quality journals'' and the difficulties associated with research and publication;
- misleading, deceptive and corrupt practices of pharmaceutical companies associated with medical research and their ability to continue to operate commercially,[41] are a small sampling of legitimate consumer grievances.

18. Medicinal cannabis is produced domestically or sourced from interstate. Much depends on available supply, quality, variety of available strains and forms (products) the ability to source a local compassionate carer/provider and a patient's personal preference.

19. The percentage of hydroponically grown cannabis to outdoor grown cannabis supplied for medicinal use in Victoria is not know. Generally speaking, hydroponically grown cannabis is considered by 58% of regular users in Victoria as having high purity and potency, with bush grown cannabis having high purity medium potency, due to variations in growing conditions.[42]

20. At times, it appears that the CCV has operated under great stress in an attempt to accommodate the compassionate needs of chronically ill and dying Victorians. Demand is customarily higher out of growing season or in times of drought, but an inability to meet demand outside of these noted periods, is largely due to an increase in the number of cannabis seizures and crops destroyed by law enforcement. The Australian Crimes Commission notes that the number of cannabis seizures in 2013-14 was the highest for the last decade.[43] Of those, 58% of the total weight of cannabis removed from the national illicit market came from Victoria.[44]

21. The number of compassionate carers or suppliers in the CCV is not known, nor are the total number of ill currently seeking and obtaining illicit supplies for medical needs. The number may be substantial based on reports from some compassionate providers.

22. Many Victorians finding their way to the CCV appear to do so, with little or no knowledge about cannabis, medicinal cannabis or medicinal cannabis products. The CCV is a welcoming, open and compassionate community ready to share its knowledge and assist those in need. Chronically and desperately ill patients often enter the community reluctantly, and sometimes with a lot of angst and inner conflict, that stepping into the community might result in legal prosecution, and not only of themselves, but also for those they love and or care for. The angst, conflict and turmoil is palatable, but faced with the prospect of continued suffering, poor quality of life or death (due to a terminal prognosis, life threatening condition or considerations of suicide) they trade the prospect of the loss of liberty for the hope of acquiring improved health. Many however, carry the angst, conflict, shame and stress with them on their journey, which contributes to the extremely stressful situation they live with daily. The learning curve is also very steep. An individual is faced with:

- acquiring knowledge on cannabis it's different medicinal forms;
- which forms and applications might have therapeutic benefits relevant to their medical condition;
- which strain of plant and combination of compounds in the plant might be suitable to their circumstances;
- whether and in what circumstances a choice for activated medicine over un-activated medicine would be appropriate and or when it would not;
- how to make the medical forms of cannabis and how to approach dosing;

- how to manage and negotiate any undesired effects associated with dose or application;
- how to fund the costs of this trial and error-process;
- how to identify quality cannabis and or cannabis products;
- how to source cannabis or a suitable medicinal cannabis product;
- how to deal with scarcity of supply and the need for continuing medication;
- how to do so without risking detection and prosecution by the law; and
- how to negotiate the impact that these matters have on personal relationships.

23. Although Victorians believe that cannabis is very easy to access [45] with more than 68% acquiring it via their social circle,[46] 32% of persons do not have access to it through this avenue and find it more difficult to access. For these individuals, they must risk having to deal with suppliers not known to the cannabis community who may provide cannabis of a questionable grade and price. Females are less likely to obtain cannabis this way due to dangers associated with the criminal world[47] and are left having to consider growing their own crops. Home grow operations, require resources, skills and an investment in additional education. A home grow operation, currently makes the person a more visible and enticing target for prosecution, as a cultivation of cannabis carries higher criminal sanctions than those associated to possessing small non trafficable quantities of cannabis[48]. Growing unlawfully causes attendant stresses associated with securing a constant supply of medicinal cannabis. It is reported that males are more likely to take this risk and establish self grow operations.[49]

24. Not all patients are in a position to grow their own medicine for a variety of reasons. Some individuals are physically incapable of doing so, do not have a secure, discrete or appropriate physical location to grow, are not confident or skilled green thumbs, or do not have the luxury of time to wait for a crop to reach harvest due to their medical conditions. These patients may be suffering acute and chronic conditions with poor quality of life, or may have been given a terminal prognosis. Faced with these issues and the obstacles referred to previously, many individuals seek out medicinal cannabis, its extracts and infusions from sources that are not known to the community. As females are less likely to obtain cannabis from a street supplier or engage in cultivation, it is thought that females with nowhere else to turn, may be left to seeking out suppliers online who supply via postal services. Unfortunately, the dangers associated with such a service are poor quality or adulterated medicinal cannabis being supplied from unknown sources, together with rorting. The CCV has received reports of rorting and sales for medicinal cannabis involving hundreds to thousands of dollar from untraceable online suppliers. Victorians who seek out cannabis for medicinal use are easy and vulnerable targets for such predatory behaviour. It is understood that many compassionate suppliers within the CCV will not charge for the medicinal cannabis they supply or will charge a fee to cover their reasonable out of pocket expenses, whilst others add on what is considered to be a fair profit for their hard work and risk taken.

25. The risk of prosecution is very real. The number of cannabis seizures in 2012-13 was the highest for the last decade. Accompanied by over 62,000 cannabis related arrests over the same time frame, this was also reportedly the highest rate for the same period ever.[50] The largest detections were reportedly via the postal service.[51]

26. Female patients and carer's seeking medicinal cannabis for themselves or loved ones may be the most at risk and or disadvantaged Victorians in being able to safely access cannabis for medicinal use.

27. For Victorians who purchase cannabis from third parties, continuity of supply is also problematic. This is not always due to seasonal factors, or scarcity of cannabis, due to high levels of crop destruction by law enforcement. The costs associated with buying cannabis to make medicines are often expensive. Patients are therefore limited by budgetary constraints. During times of scarcity, prices on the street can escalate, leaving patients without medicine. This can have life threatening consequences for some patients, and can result in patients receiving much less than they require. In 2013, the price of a gram of hydroponically grown cannabis head sold between $12 and $50; one ounce of cannabis, ranged between $250 and $450, while the price for a mature hydroponic cannabis plant was between $2,000 and $5,000. In fact, the street prices for drugs such as cannabis in Australia, is more than double the global average according to The Global Drug Survey of 2015[52]. Many chronically ill patients lose their employment and if eligible, and sometimes after a lengthy wait for approval, survive on a small disability support allowance. The current single allowance is $430 a week.[53] It is increasingly common to hear reports of chronically ill medicinal cannabis patients spending their entire disability support allowances on cannabis to ensure they have some cannabis medication to provide them with relief from their suffering. The quantity of medicinal cannabis needed to achieve this, varies according to the ailment and its severity. A patient that requires 28 grams of cannabis per week, will need $336 (28 grams at $12 per gram) to relieve their suffering. Patient's, who find themselves in this position, forego rent, food and other life sustaining essentials, include personal and intimate relationships. Sadly, many relationships suffer either from prejudice associated with medicinal use and or, an inability to participate in social activity due to constraints on finances. Patients in these circumstances are known to turn to home grow or cultivation operations .A recent case[54] before the Supreme Court, in the ACT supports what the CCV commonly witness. The accused in this matter began to smoke cannabis to address the pain and side effects he suffered from chemotherapy and surgery associated with bone cancer. His medicinal cannabis requirements were expensive and resulted in him becoming a caretaker of a cultivating operation in order to pay for his medicinal cannabis. The accused was sentenced to 28 months jail. People experiencing great pain and or suffering, will often go to great lengths to find relief. In such circumstances the law, food and shelter, become secondary considerations.

28. Medicinal cannabis is a life-sustaining medicine. This is clearly evident in the cases of children with severe forms of Epilepsy. It is submitted that the right to the provision for adequate health care, life, liberty and a reasonable economic standard of living are fundamental human rights. Victorians are currently using medicinal cannabis to address threats to their health and life, and seek to bring an end to their need to suffer or self-medicate illegally and without the support of their doctors, because the law has not kept pace with science and societal needs. Prosecutions, together with the destruction of crops are currently denying seriously ill Victorians a life sustaining and healing medicine, and destroying individual lives and families in the process. Whilst Victorians wait for the establishment of a regulated medicinal cannabis scheme, Victorian patients continue to die or have their lives ruined by the existing laws of prohibition. Members of the CCV are calling upon the Victorian government to introduce interim measures to protect patients, their carer-providers and suppliers from prosecution and any form of legal process without further delay. Patients being denied lawful access to medicinal cannabis is contrary to the spirit and intent of the UN Single Convention on Narcotic Drugs 1961 and denies Victorias a number of acknowledged

human rights. Consequently, this submission supports the operation of a legal amnesty and provides recommendation for the immediate implementation of the same. The Commission is referred to “Operation and Implementation of a Legal Amnesty” in this submission.

29. Compassion requires that suc be attended to immediately and that lawful access under a carefully considered regulatory medicinal cannabis scheme must be given to as many Victorians in genuine need, or who in the words of the UN Single Convention on Narcotic Drugs 1961, are in pain and or are suffering. Anything short of this, will lead to a growth in the illicit market and litigation against the Victorian and federal governments domestically, with the filing of complaints to the United Nations about Australia’s non-compliance with its international treaty obligations.

30. Whilst popular viewpoints might not be a substitute for rational science, they represent the needs and will of the Victorian and Australian people. It is the voice of the people who drive reform and who shape the nature of the society we live in. It is the same voice that also recognises the shortcomings and limitations of science, and its associated regulatory systems, which remain unresponsive to changing times, and peoples needs. The CCV is committed to bringing in necessary and long over due changes in relation to cannabis reform and in doing so, challenges the scientific community and regulatory authorities to become more responsive and relevant to 21st century needs of Victorians.

PART TWO

CANNABIS AS A SAFE FOOD & MEDICINAL

CANNABIS AS A SAFE FOOD & MEDICINAL

1. Cannabis is an herbaceous plant that has been favoured and employed by mankind for centuries for many nutritional, medicinal, spiritual and industrial uses.
2. It's use has only been curtailed, tightly controlled and prohibited with the introduction of the laws of prohibition in the twentieth century.
3. Cannabis belongs to the family Cannabaceae, the genus Cannabis and is divided into three species: C Sativa, C Indica and C Ruderalis.
4. The plant produces a number of chemical substances, which include a number of psychoactive and non-psychoactive components found in resin in the female flower of the plant.[55] It is due to the presence of the psychoactive properties of the primary cannabinoid THC that the plant is a legally prohibited and controlled substance.
5. This is quite unfortunate, as properties in the plant referred to as ''cannabinoids'' mimic naturally occurring substance in the human body, which have even been found occurring naturally in human breast milk.[56] Cannabinoids work synergistically together with other properties in the plant, interacting with the endogenous cannabinoid system in the human body via receptors (CB1 and CB2) located in the human brain and throughout the body), working together to bring the body back to homeostasis and good health. It is believed that many of today's illnesses may be due to imbalances and or deficiencies in the endogenous endocannabinoid system in the human body.[57]

CANNABIS AS FOOD

1. The ancient use of cannabis for such purposes has been well documented.

- The Chinese pharmacopoeia (Pen T'sa Kang Mu) compiled y Li Shih Chen referring to authors dating back many centuries references cannabis seed as food and medicine.[58]
- 1000 BC, references have been made to Bhang in ancient India, the term used for a popular cannabis-infused food.[59]
- Referenced in the Hindu Vedas between 2000 and 1400 BC, in the Atharva Veda. It was referred to in India as "food of the gods" and is known by Hindus as the "gift of Shiva" (who is considered their supreme god and who allegedly used cannabis to aid his meditations).[60]
- Today cannabis leaves are used in traditional local foods and cannabis seed is still eaten by the poor in India and Nepal. It is said to make vegetables more palatable and complete foods. [61]
- 130-200 AD Claudius Galen an ancient Roman physician made reference to a cannabis-infused dessert, popular at the time, which is believed to have included whole flowering tops of the plant.[62]
- 6th century BC Persians enjoyed a preparation of cannabis seed referred to as ''Sahdanag'' or ''Royal Grain''. [63]
- This was later adopted by the Hebrews who were already aware of many uses for the plant they called ganeh-bosm (the root word from which the name cannabis is derived). The Hebrew word, Tzli'q, (Tzaddi, Lamed, Yod, Quoph) is said to reference a Hebrew meal of roasted cannabis seed that was sold in European markets during medieval times.

- Throughout this period China regarded cannabis seed as one of seven main staple grains, where it was consumed in a variety of ways up to the 6th century AD. [64]
- 500-1500 AD porridges, gruels and soups of cannabis seed, were popular. Monks were required to consume cannabis seed dishes three times a day.[65]
- In twentieth century, cannabis and its seeds had been consumed as a food source in some European and African countries, all oriental countries, as well as Russia. It was a notable staple food during times of famine. [66]
- A soup made from cannabis seeds known as "semientiatka" is eaten on Christmas Eve in Poland and Lithuania. A similar meal is also enjoyed in Latvia and Ukraine in celebration of ''Three Kings Day'' thought to be a historic reference to the 6th century Persian King's "Royal Grain".[67]
- Suto women of South Africa grind up cannabis seed with bread or mealie pap to give to children when they are being weaned from the breast. Interestingly, cannabis contains gamma linoleic acid, a substance also found in human mothers milk.[68]
- Cannabis and its seed have a long history of use as animal feed and are believed it could provide a complete dietary source for animals.

2. Cannabis contains ''globule edestins'' which are similar to the globulin found in human blood plasma. It has been hailed as ''natures perfect food for humanity'' containing the most balanced and richest natural source of essential oils for human consumption. [69]
3. 1955 Czechoslovakian Tubercular Nutrition Study concluded that cannabis seed was ''the only food that can successfully treat tuberculosis, where the nutritive processes are impaired and the body wastes away.[70]
4. A variety of the cannabis plant is Hemp. Hemp cannabis contains lower levels of THC (delta 9-tetrahydrocannabinol), the chemical associated with the psychoactive properties of the cannabis plant and higher levels of CBD.
5. Hemp cannabis seeds contain protein, polyunsaturated fatty acids. vitamins and minerals. The Australian government recognizes cannabis as food and states that it may provide an alternative dietary source of these nutrients.[71]
6. Cannabis seeds are a rich source of dietary minerals including Magnesium (160% DV), Zinc (77% DV), Iron (53% DV) as well as a good source of dietary fibre (13% DV) and 73% of their weight is made up of fats and essential fatty acids – consisting mainly of polyunsaturated fatty acids, linoleic, oleic and alpha-linolenic acids. [72]
7. Hemp proteins have a PDCAAS Protein Digestibility Corrected Amino Acid Score value (measuring which foods are complete proteins for humans) equal to or greater than certain grains, nuts, and some legumes.[73]
8. Hemp cannabis seeds and plant as a food, can be eaten raw (seeds – hulled or dehulled, grain and fresh leaves in salads), ground into a meal or flour, cake, protein powder, sprouted, made into hemp milk, or prepared as tea, oil or butter, and incorporated into other foods.[74]
9. The cannabis plant has long been regarded as a satisfying and nutritious food source. Modern science knows that it contains all the essential amino and fatty acids necessary to sustain human life. The amino acid profile is comparable to protein derived from meat, milk, eggs and soy,[75]and is used outside Australia as an important dietary supplement for those who enjoy a vegetarian or vegan diet.
10. The plant provides 73% of the Daily Value (DV) of protein in a 100 g serving and are

notable as a high protein food source[76]

11. Hemp and cannabis leaves, seeds, resins and food products made from the same are very low in THC so do not present any safety concerns as food.

12. This was confirmed in 2012 by The Australian and New Zealand Ministerial Forum on food regulations. Food Standards Australia and New Zealand (''FSANZ'') found ''that foods derived from the seeds of low THC hemp do not present any safety concerns as food''. [77]

13. In spite of this finding, cannabis seeds cannot presently be used in food in Australia and New Zealand as it is prohibited in the Australia New Zealand Food Standards Code. However, hemp seed oil is permitted in NZ since 2002 under the New Zealand Food (Safety) Regulations.[78] A decision to change the scheduling of cannabis as food was deferred due to concerns regarding the degree to which, such low THC foods might interfere with roadside drug testing kits.[79]

14. In addition to a safe and nutritious food, cannabis has been used as a medicine to prevent and treat a wide range of medical conditions in humans and animals for many centuries.

15. The ancient use of cannabis for such purposes has been well documented.[80]

CANNABIS AS MEDICINE

- In the form of an anointing oil, cannabis is mentioned in the book of Exodus in the Bible.[81]
- Referenced in China (2700 BC) as an important herbal remedy by the father of Chinese medicine, Emperor Shen-Nung [82] and was found in the first Chinese pharmacopoeia, the Pen-ts'ao Ching in which it was recommended for symptoms and conditions arising from a deficiency in 'Yin' energy, including mental fatigue, rheumatism, malaria, beriberi disease, constipation and absent-mindedness. It was recommended in ancient China for use in more than 100 medical symptoms and conditions.[83]
- In 2008, archaeologists discovered over two-pounds of cannabis in the 2,700-year-old grave of an ancient shaman in Central Asia. Testing of the materials potency led to the conclusion that that ancient cultures cultivated cannabis for medicinal and other purposes.[84]
- Referenced in India from the second millennium BC in the Veda.
- Referenced in the tablets from the Royal Library of Ashurbanipal an Assyrian King, who lived around 650 BC .[85]
- 550 BC Zoroaster, a Persian prophet gives cannabis prime place in the sacred text the Zend-Avesta which lists over 10,000 medicinal plants.[86]
- 23-79 AD Roman historian Pliny referenced cannabis seed oil's use to extract "worms from the ears, or any insect which may have entered them." [87]
- 70 AD Dioscorides, the Roman Emperor Nero's surgeon praises Cannabis for its medical properties.[88]
- 865 -925 AD Mohammed-e-Zakaria-ye Razi a Persian physician references wide-ranging uses for cannabis as a medicine.[89]
- 1000 AD Moslems produce hashish for medicinal and societal use.[90]

- 500-1500 AD Cannabis was a key ingredient in therapeutic applications and complex recipes were referenced including the "Pelotus of Antioch" (the pellet or pill of Antioch). It was used as a topical salve in the form of an ointment. The medieval nun and poet Hildegard of Bingen recommended its use for the relief of pain.[91]
- 15-16th Century –commonly referenced in medicinal recipes in England. The records of the St John the Baptist Hospital in Winchester reference 36 gallons of cannabis seed being purchased "for the use of the sick." [92]
- In 'Complete Herbal', Nicholas Culpeper (1616-1654) recorded that a cannabis preparation was used to ease the suffering of colic, bowel problems and to stop "bleeding at the mouth, nose and other places." [93]
- 1770 Cannabis seeds were introduced into Australia by Sir Joseph Banks, a botanist on Captain Cook's voyage to Australia.
- 1794 -The Edinburgh New Dispensatory referred to an emulsion of cannabis seed oil in milk, given as a cough elixir as well as a treatment for venereal disease.[94]
- Homeopathy journal American Provers' Union publishes first of many reports on the effects of cannabis.[95]
- 1841 Dr. W.B. O'Shaughnessy of Scotland introduces cannabis to Western medicine after working in India. In the following 50 years hundreds of medical papers are written on the medical benefits of cannabis.[96]
- 1843 reference was made to cannabis as a medicinal in the USA, and was included in the US dispensary list of medicines a few years later in 1852.[97]
- Abel citing Wood & Bache 1854 list it as a treatment for "'neuralgia, gout, tetanus, hydrophobia, cholera, convulsions, chorea, hysteria, depression and insanity".[98]
- 1870 US Pharmacopoeia lists it as a medicine for various ailments.[99]
- 1890 Queen Victoria's personal physician Sir Russell Reynolds prescribes cannabis for her menstrual cramps. In the first issue of The Lancet he reports that cannabis "When pure and administered carefully, is one of the of the most valuable medicines we possess"[100]
- A wide variety of cannabis products (both prescription and over the counter) were popular in Australia and New Zealand in 1800s, demonstrating its widespread use even though the effectiveness of products varied widely due to limited understanding of the lipid-solubility of its active components.
- 1895 The Indian Hemp Drug Commission concludes that cannabis has some medical uses, no addictive properties and a number of positive emotional and social benefits.[101]
- 1925 The 'Panama Canal Zone Report' analysing cannabis use by soldiers concludes that there is no evidence that cannabis use is habit-forming or deleterious. The report recommends that no action be taken to prevent the use or sale of cannabis.[102]
- Cannabis and in particular tinctures of cannabis were used in Australia up until the 1960s (the most common preparation was a solution of black Nepalese hashish dissolved in formaldehyde).[103]
- 1990 discovery of THC receptors in the human brain is reported in scientific journal Nature. [104]

THE TAXONOMY PHARMACOLOGY & THERAPEUTIC BENEFITS OF CANNABIS

TAXONOMY PHARMACOLOGY & THERAPEUTIC BENEFITS

TAXONOMY

1. Cannabis is a hardy annual flowering herbaceous plant.
2. It belongs to the family "Cannabacae,'' and is assigned for taxonomical purposes into three species: Sativa, Indica and Ruderalis. Modern "hybrid" strains are a result of selective inter-breeding of these primary strains to produce strains that blend the physical and medical qualities of the parent strains.[105]
3. Cannabis Sativa (tall and narrow leafed plant) which can grow to a few meters in height and which are best known for their uplifting and energising effects.[106]
4. Cannabis Indica (short, conical shape, wider leaf than C. Sativa).[107] This shorter species is said to be better suited for indoor growing due to smaller space requirements and shorter flowering periods. Most cannabis grown illegally is from Indica trains because the growers are exposed to being caught for shorter periods. The prevalence of Indica strains is responsible for the stereotype, that cannabis make users lazy and/or sleepy.
5. Cannabis Ruderalis (short and smaller than C Indica), branchless, grows wild in Asia[108]
6. Indigenous to Central and South East Asia, Cannabis Sativa is found to grow naturally in tropical and humid parts. Cannabis plants are now grown outdoors successfully throughout the world, including in Australia.[109]
7. Pollination is by wind between male and female plants, and produces achene fruit (seed).[110]
8. Many sexual phenotypes that can be described in terms of ratio of female to male flowers in the individual plant, or in the cultivar are found in the cannabis plant. [111] For drug production the flowers and leaves of female plants are primarily used.
9. Life period of the plant when grown outdoors is from April to September: in the northern hemisphere or September to March in the southern hemisphere.[112]
10. A female plant produces multiple small flowers, which form a large bud at the top of the plant. These flowering tops or buds have the highest concentrations of the psychoactive and medicinal cannabinoid tetrahydrocannabinol or "THC", with leaves, stalks and seeds having lower concentrations.[113]
11. The United Nations states that leaves can contain ten times less THC than the buds, and the stalks one hundred times less THC.[114]
12. The flower also contains a number of ''trichomes''. These are gland like cells, which contain resinous oil. This oil contains high quantities of THC. The percentage of THC increases notably as the season changes from summer to autumn.
13. Cultivation is by way of cloning to ensure all plants are genetically the same as the "mother plant''. This process can take anywhere from 5-21 days. Cultivating is also used to select the best genetics. This is achieved by selecting one or more strains, growing a number of plants to see which exhibit the desired characteristics including pharmacological properties, increased yield, resistance to pests, reduced time to fruition, geometric traits (flower density, uniformity, compactness, etc.), trichome density and type (stalked or sessile), flavour and/or aroma due to terpenes (controlling the levels of these important modulators of THC) and colour.

14. Cross cultivation of more than one strain (''hybrids") is also done to produce healthier, stronger and quicker growing plants. The main reason for hybridisation has traditionally been to create strains that provide particular bodily and/or cerebral effects. Strains are cultivated according to their intended use. Male plants will often be separated from females in a process called sensimila (or "without seed"). This prevents the fertilization of the female plants, giving control over selecting an appropriate male plant. Pollen from the male is collected and stored until needed. Pollination results in seeds of F1 hybrids, with resulting offspring differing from, but having characteristics of both. Repeated breeding over successive generations results in characteristics appearing more regularly and produces genetic stability and certainty in plant characteristics and properties.

15. There are numerous strains of cannabis currently available as a result of cultivation practices of this nature.

16. C. Sativa strains are known for their cerebral effects, and are employed as a daytime use medicine, while S. Indica being well known for its sedative effects are used mostly as a night time medicine (or for daytime use by those who need rest through sedation), with hybrid strains providing stronger mental clarity or more being sedentary, depending on whether their breeding is more Sativa or Indica-dominant.[115]

PHARMACOLOGY

1. C. Sativa is reported to have high concentrations of THC which is responsible for euphoric and psychotropic effects when consumed excessively, and also non-psychoactive compounds such as cannabidiol (CBD), cannabinol (CBN) and cannabigerol (CBG) as well as terpenes such as pinene and lemonene which all modulate the effect of THC to create an "ensemble effect".[116]

2. C. Indica is also reported to have high concentrations of THC however euphoric and psychotropic effects are usually dampened by high concentrations of the analgesic terpene Mycene that causes an overall sedentary effect.[117]

3. C. Ruderalis has only trace amounts of THC, but is high in the non-psychoactive component, cannabidiol.

4. Due to hybridization of gene pools, most C. Sativa and Indica strains are rich in THC.[118] The quantitative percentage and the general cannabinoid profile of the plant is often determined by gas chromatography, sometimes combined with mass spectrometry. Liquid chromatograph techniques can, unlike gas chromatography, differentiate between the acid and neutral forms of the cannabinoids.

5. There are hundreds of distinct compounds in the plant itself. 489 distinct compounds in 18 different chemical classes, with at least 85 different cannabinoids exhibiting different effects[119] which are to be found in the leaves and flowering tops of the plant.[120] The plant contains the following chemical classes, many of which are commonly found in foods: -cannabinoids, non-cannabinoid phenols, terpenes, flavonoids, nitrogenous compounds, proteins, amino acids, enzymes, glyco proteins ketones, acids, fatty acids, vitamins, alcohol, aldehydes, esters, steroids, lactones and pigments.

6. There are over 200 terpenoids in the cannabis plant including: a-pinene, B-Caryophyllene, Borneol, Caryophyllene Oxide, Cineol, Citronellol, Humulene, Limonene, Linalool, Myrcene, Nerolidol, Phytol and Terpinolene.[121]

7. In vitro and vivo studies, as well as clinical trials in humans[122] attribute terpenes with: anti-inflammatory, anti-oxidant, anti-anxiety, anti-microbial, anti-fungal, anti-septic, anti-malaria, anti-neoplastic, anti-depressant, anti ischemic, anti-spasmodic, anti-convulsant, and anti-insomnia properties. The alleviation of depression in human trials, by using a citrus scent, strongly suggests a synergistic benefit between terpenes and phytocannabinoids.[123] B-Linalool has been used in the treatment of psychosis, anxiety, as an antiepileptic agent and analgesic.[124] Limonene has been used as a gastric reflux medication, whilst some other terpenes form the basis of current pharmacological drugs such as the anti-cancer drug, Taxol and anti-malarial drug, Artimesinin.[125] Many terpenes offering therapeutic promise are too structurally complex to be extracted or synthesized in a cost effective manner from commercial quantities of plant material, which contributes to the absence of clinical trials.
8. The varying concentrations of these terpenes found in cannabis modulate its overall effect, for example Myrcene makes cannabis users sleep (i.e., for healing cancer), Lemonene is uplifting (i.e. for depression and anxiety disorders) and Pinene is helpful for concentration (i.e. for ADHD) and attenuates the memory loss effect of THC (which can be useful for forgetting bad memories in PTSD, but which is not always a desired effect for sufferers of other conditions).[126]
9. The presence and abundance of cannabinoids and other properties such as terpenes vary primarily according to strain, with quantities/yield produced varying largely based on growing conditions, and the way the plant is processed and or used. [127]

CANNABINOIDS

1. Cannabinoids are a class of chemical. There are 3 types: endocannabinoids (natural occurring and produced by the human body and animals), [128] phytocannabinoids (found in plants) and synthetic cannabinoids (manufactured pharmacological substances that mimic or modify the structure of naturally existing cannabinoids).
2. There are three principal cannabinoids in the cannabis plant: tetrahydrocannabinol (THC), cannabinol (CBN) and cannabidiol (CBD), though others, which occur in less significant quantities, such as tetrahydrocannabivarin (THCv) and Cannabigerol (CBG), also have significant medicinal value.
3. When consumed, cannabinoids found in the cannabis plant lock onto receptors on cells in the body interacting with the human body's ''endo-cannabinoid system''.
4. The endocannabinoid system is responsible for the regulation of homeostasis, and is arguably the most important system in the human body [129] The human endocannabinoid system can be supplemented using the cannabinoids found in the cannabis plant, which also produce various medicinal effects.
5. Although an emerging area of science, it is presently understood that the endocannabinoid system modulates immunity, inflammation, apoptosis (the selective destruction of cancer cells), carcinogenesis, pain, neural-plasticity, neuro-protection, emotions, memory, hunger/feeding and embryological development.[130]
6. Dysfunction and or the presence of these conditions have been suggestive of an endocannabinoid deficiency.[131]
7. A review that examined 184 in vitro studies, 102 in vivo animal studies, and 36 human studies concluded that a number of properties acted upon the endocannabinoid system and that when activated –THC, the cannabinoid responsible for producing euphoric sensations and psychosis in some people, in fact modulates the

endocannabinoid system. Despite its psychoactive properties, THC is undoubtedly, a vital, synergistic therapeutic component, which must be present to bring about healing via the modulation of the human cannabinoid system.[132]

8. A number of common pharmaceuticals including: analgesics (acetaminophen, non-steroidal anti-inflammatory drugs, opioids, glucocorticoids), antidepressants, antipsychotics, anxiolytics, and anticonvulsants, are known to up-regulate the endocannabinoid system. It has been suggested, that cannabis can also work synergistically for clinical purposes, with these common pharmaceuticals enhancing therapeutic outcomes.[133]
9. Cannabinoids in the cannabis plant and specifically THC, can play an important role in the regulation of homeostasis and enhanced clinical therapeutic outcomes.
10. The modulatory effect of THC on homeostasis in the body, together with a range of therapeutic outcomes are due to the cannabinoid properties of the plant locking onto specific receptor sites in the body known as “CB1” and “CB2”. Cannabinoids in the cannabis plant activate these receptors. When activated, these engage multiple inter-cellular signal pathways.
11. CB1 receptors are most abundant in the brain, peripheral nerves and autonomic nervous system (though they are found in peripheral tissue and cells elsewhere in the body). CB2 receptors are found mostly in the immune and haematological cells of the body controlling immune regulatory functions.[134]
12. For all these reasons, cannabis is promoted as a first line treatment by medicinal cannabis scientists, physicians and therapists.

PSYCHOTROPIC CANNABINOID: THC

1. (−)-trans-Δ^9-tetrahydrocannabinol ((6aR,10aR)-delta-9-tetrahydrocannabinol), or simply ’THC’’ is the cannabinoid responsible for the primary medicinal effects and in higher doses psych activity.
2. THC, was first isolated in 1964 by Israeli scientists Raphel Mechoulam and Yechiel Gaomi at the Weizmann Institute of Science.[135]
3. THC mainly occurs in its acidic non-psychotropic form tetrahydrocannabinolic acid or THCa (THCA, 2-COOH-THC or tetrahydrocannabivarinic acid) together with other cannabinoids and compounds. THCa in and of itself is not psychoactive.
4. THC acids: THCa and THCVa, (together with some other cannainoids in their acid state such as CBDa, CBNa and CBGa) are non psychotropic and are known for their anti-cancer, anti-inflammatory and anti-spasmodic properties.[136]
5. THC acts primarily on CB1 receptors located in the brain, which produces a significant psychotropic result. However, it has also been found that THC has an equal affinity for CB1 and CB2 receptors.[137] Consequently, THC also provides some of the therapeutic benefits associated with the non-psychotropic cannabidol (CBD).
6. However, this only occurs when the neutral THCa found in the raw plant is ‘activated’ to become THC delta 9 by a process referred to as ‘’decarboxylation.”
7. Decarboxylation results when carboxylic acids loses a carbon atom from a carbon chain, releasing carbon dioxide (CO_2) converting the acidic THCa to THC delta 9 in the process. This happens naturally during exposure to light/heat and / or drying, which is usually a slow process over time. Decaboxylation can also be completed

quickly however, when the plant is subjected to heat at or above a specific temperature for a specified period of time. Decarboxylated cannabis product and medicines that have been subjected to this process are referred to as ‘’activated’’ cannabis products/medicines.

8. Consuming the raw plant as food or processing it without subjecting it to heat or a decarboxylation process, fails to activate a potent psychotropic THC medicine. Although THC may be present in the plant due to exposure to natural heat/light/drying, the psychotropic and medicinal property in THC in the plant prior to the decarboxylation process referred to is not comparatively, pyscho active in any real potently effective way.[138]

9. THC(a) in inactivated products are without effective and potent psychotropic effect, as THCa itself, is not psychotropic.[139]

10. Inactivated cannabis products/medicines containing the acidic non-psychotropic cannabinoid acid THCa that have not been subject to decarboxylation process, are popularly employed for treating children and patients who wish to avoid the possibility of and or who may have difficulty managing, any undesired strong psychotropic effects associated with THC.

11. THC-Acid when aged or degraded breaks down into the non-psychotropic cannabinoid acid Cannabinolic Acid or CBNa. This cannabinoid is known for its anti-inflammatory properties.[140]

12. THC is metabolized mainly to 11-OH-THC by the body, where it remains psychoactive and is further oxidized to 11-nor-9-carboxy-THC (THC-COOH). Metabolism occurs mainly in the liver. [141]

13. 11-COOH-THC does not have any psychoactive effect but, plays a role in the analgesic and anti-inflammatory effects of cannabis,[142] and has also been shown to moderate the effects of THC itself.[143]

14. THC and THCV together with other chemical properties in the plant, work together synergistically to provide therapeutic effects. Referred to as the ‘’entourage effect.’’ THC is known to be an analgesic, muscle relaxant and antispasmodic,[144] and has 20 times the anti-inflammatory power of aspirin and more than twice that of hydrocortisone.[145]

15. THCV has been shown to demonstrate prominent antiepileptic actions, [146] in the formation and healing of bone fractures[147] and anti-proliferative/pro-apoptotic effects on cancer cells[148]. It has also been shown to provide relief for strong inflammatory associated pain[149].

16. THC also mimics the action of the naturally occurring neurotransmitter “anandamide’. Acting on CB1 receptors in the brain, THC has also been found to be neuro-protective; have the potential to reduce neuro-inflammation and to stimulate neurogenesis.[150] It is also has anti bacterial, anti cancer, anti convulsive effects, as well as an appetite and bone stimulant.[151]

17. THC that has degraded through age, UV light, oxidation and isomerization, breaks down into delta-8-tetrahydrocannabinol as well as the non-psychoactive cannabinol or CBN. Delta 8 tetrahydrocannabinol has anti anxiety and antiemetic properties, whilst CBN is known for its analgesic, antibacterial, anticonvulsive, anti inflammatory, anti insomnia and anti-inflammatory properties.[152]

18. THC has low solubility in water, but good solubility in the body is achieved when it is ingested with lipids or alcohol. Its bioavailability and effect depends on a number of facts including: the form, method and route of application, genetic strain of plant and

concentrations of THC, and the quantity and quality of substances employed in conjunction with it including fat, alcohol and other medications.

19. Its duration in the body also varies accordingly, and similar to other chemical compounds, there will be variation according to individual metabolism, frequency of use and/or previous exposure/tolerance.

20. Its effects may be safely managed and modulated by a consideration of these factors, together with attention to dosage.

NON PSYCHOTROPIC CANNABANOIDS

1. Many weak psychotropic and non-psychotropic cannabinoids are found in the cannabis plant.

2. The principal weak and non-psychactive cannabinoids are:Tetrahydrocannabinolic Acid or (THCa) D^9 Cannabidiol (CBD), Cannabichromene (CBC) Cannabinol (CBN) and Cannabigerol (CBG) Cannabidivarin (CBDV) and Cannabidiolic acid (CBDA)[153] Others include:

    - Cannabidivaric Acid (CBDVa)
    - Cannabigerivarinic Acid (CBGVa)
    - Cannabigerivarin (CBGV)
    - Cannabinolic Acid (CBNa)
    - Cannabichromic Acid (CBCa)
    - Cannabichromivaric Acid (CBCVa)
    - Cannabichromivarin (CBCV)
    - Cannabicyclol Acid (CBLa) and
    - Cannabicyclol (CBL). [154]

TETRAHYDROCANNABINOLIC ACID (THCA)

1. THCa begins to convert to THC immediately after harvest and the process is accelerated by light or heat, but in and of itself, it has no psychotropic activity in its own right. Whilst THC has long been associated for its ability to reduce nausea, recent research has found that as an antiemetic (anti nausea and vomiting), THCa is far more effective than THC.[155]
2. It is also shown to have anti proliferative effects;[156] it is a strong anti-inflammatory[157], neuro protectant[158] and anti spasmodic[159] in its operations. Medicinal cannabis patient organisations overseas, speculate that these factors may well be why, patients using THCa are reporting success in controlling seizure activity.[160]There are many children with pediatric forms of epilepsy currently taking THCa based cannabis medicine in Australia, with great success.

CANNABIDIOL (CBD)

1. CBD is the most common phytocannabinoid found in the industrial hemp plant.
2. CBD does not activate CB1 and CB2 receptors.[161] It acts as an indirect antagonist.
3. CBD has found to modulate the effects of THC therefore eliminating or mitigating against undesired potent psychotropic and other activity: such as anxiety, tachycardia, hunger and sedation. [162]
4. CBD has shown promising results in clinical studies that identify it as a treatment for schizophrenia. It has also been reported as having anixolytic and antidepressant effects.[163]
5. Suggestions reported by the VLRC at paragraph 2.22 that some high CBD users having reported mild psychoactive effects, are difficult to explain other than possible poor strain selection or an error in identification of such.
6. CBD provides a wide range of therapeutic actions, including anti-inflammatory, anti nausea, anxiolytic, convulsion, analgesic and neuro protective properties (and has been shown to reduce the risk of stroke and improve cognition).[164]
7. It has been noted to play a role in turning off mutant genes such as the ID1 gene responsible for metastasis cancers, including aggressive forms of breast cancer and being cyto-preservative for healthy cells.[165]
8. CBD antagonises TNF-a in rheumatoid arthritis[166] and decreases oxidative damage in the body.[167]
9. CBD has shown reduction of β-amyloid in Alzheimer's disease and has demonstrated powerful activity against methicillin-resistant staphylococcus aureus (MRSA)[168]
10. CBD in its acidic form (CBDa) is also known for its: analgesic, anti inflammatory, anti cancer, anti fungal properties. [169]
11. When cannabis is decarboxylated, CBD is known for the following properties: analgesic, anti anxiety, anti bacterial, anti cancer, anti convulsive, anti depressant, anti emetic. anti inflammatory, anti insomnia, anti ischemic, anti psychotic, anti -spasmodic, bone stimulant, immunosuppressive and neuro protective. [170]

CANNABIGEROL (CBG)

1. Cannabigeriolic acid (or CBGa) is the precursor to the formulation of all other cannabioids including CBG, THC & THCa, CBD & CBDa, CBC & CBCa, CBL & CBLa, THCv and THCva, CBDv and CBDva .[171]

2. Specifically, the acidic CBG(a) in the plant and in inactivated products is the precursors to the formulation of :

    - THC (a) which becomes THC upon activation[172]
    - CBD (a), and CBDV (a): which become CBD and CBDV on activation[173]
    - CBC (a) and CBCV (a): which becomes CBC and CBCV on activation and later CBL[174] and CBL (a) upon degradation[175]

3. CBG together with other chemical properties in the plant work together synergistically (referred to as an “entourage” or “ensemble” effect) to provide therapeutic benefits.
4. CBG (a), CBGV (a) and CBG are known for their analgesic[176], anti inflammatory[177],

anti bacterial[178], anti cancer[179] (most effective cannabinoid for breast cancer after CBD)[180] anti depressant[181], anti fungal[182] muscle relaxant[183], anit hypertensive[184] and bone stimulant properties. [185]

CANNABINOL (CBN)

1. Cannabinol or CBN is a by-product of THC degradation through oxidation. [186]

2. CBN together with other chemical properties in the plant work together synergistically to provide therapeutic benefits, which include: anti inflammatory, analgesic, anti bacterial, anti convulsant, anti insomnia.[187]

CANNABICHROMENE (CBC)

1. Cannabichromic Acid (CBCa) are found in the raw plant and or in inactivated products. CBC (a) and CBV (a) become Cannabichromene (CBC) and Cannabichromivarin (CBDV) on activation.

2. CBC is at optimal levels at early stages in the plants development cycle and new cold water extraction from techniques from immature leaf material of specially bred strains, yield high ''enriched trichome preparations'' of CBC[188].

3. CBC is said to have, cytotoxicity to cancer cells[189] analgesic[190] anti depressant[191] anti biotic[192] and anti fungal[193] and anti-inflammatory properties[194]. It has also shown to reduce THC intoxication, once again demonstrating the entourage effect at work in the plant. [195]

SAFE & EFFECTIVE USE OF CANNABIS

SAFE & EFFECTIVE USE OF CANNABIS

1. Cannabis is a prohibited and controlled substance and classified as a poison under state, federal and international laws[196]. It is regulated as a poison, a controlled substance and consequently, a drug of misuse, which attracts criminal sanctions.
   It is not however, a narcotic, even though it was deemed one for the purposes of International and domestic law.

2. There is no scientific evidence, which demonstrates that cannabis is a poison. In fact, it has an extraordinarily low toxicity profile.

3. Dr Lester Grinspoon is an Associate Professor of Psychiatry (Emeritus) at Harvard Medical School. He was a senior psychiatrist at Massachusetts Mental Health Center in Boston for 40 years, a fellow of the American Association for the Advancement of Science and the American Psychiatric Association, as well as the editor of a number prestigious scientific journals and author/co-author of a number of books on cannabis. He has also testified before the USA Congress on the safe and effective use of cannabis and is regularly called upon, both domestically and internationally, as an expert on this subject.

4. Dr Grinspoon began to study cannabis in the 1960's expressing the view that cannabis:

   "was a very harmful drug that was unfortunately being used by more and more foolish young people who would not listen to or could not believe or understand the warnings about its dangers.''[197]

5. In his attempt to ''define scientifically the nature and degree of those dangers" he surprisingly found himself concluding that the general public had been misinformed and misled. He found that there was ''little empirical evidence'' to support his initial beliefs about the dangers of cannabis and it was much less harmful than he had believed.[198] He states:

   "There is no question about its safety. It is one of humanity's oldest medicines, used for thousands of years by millions of people with very little evidence of significant toxic effects. More is known about its adverse effects than about those of most prescription drugs."[199]

6. To illustrate that point, the following list represents the top 10 pharmaceutical drugs by cost, to the Federal Government in Australia and the number of studies associated with them[200]:

   - Rituximab 2,892
   - Clopidogrel 9,519
   - Simvastatin 7,963
   - Olanzapine 7,031
   - Atorvastatin 6,534
   - Adalimumab 3,974
   - Fluticasone 3,406
   - Salmeterol 2,460
   - Rosuvastatin 2,237

- Ranibizumab 1,999
- Esomeprazole 1,023

7. By contrast, the number of PubMed (US government repository for peer reviewed scientific research) studies on cannabis is 20,497.[201]

8. Of the 20,497 scientific studies on cannabis, half of this vast body of medical scientific literature has emerged in the last five years alone. The growth has been directly attributed to the testimonials reported by medicinal cannabis patients to their physicians in overseas jurisdictions.[202]

9. In 2010 The University of California Centre for Medicinal Cannabis Research, conducted a series of randomized placebo controlled clinical trials, which accorded to the FDA gold standard for clinical control design on the medical utility of inhaled cannabis. The Centre's report on its studies concluded, that cannabis should be "a first line treatment"" for patients with neuropathy and other serious illnesses. [203]

10. A summary of the Centres trials published in 2012 in the Open Neurology Journal concluded: "Evidence is accumulating that cannabinoids may be useful medicine for certain indications. ... The classification of marijuana as a Schedule I drug as well as the continuing controversy as to whether or not cannabis is of medical value are obstacles to medical progress in this area. Based on evidence currently available the Schedule I classification is not tenable; it is not accurate that cannabis has no medical value, or that information on safety is lacking." [204]

11. Reviews[205] of controlled clinical trials (randomized, double blind, placebo controlled) evaluating the safety and efficacy of standardized pharmaceutical grade, synthetic pharmaceutical and natural phytocannabinoids flowers) have reported favorable findings associated with cannabis use in the following medical conditions, which include but are not limited to:

    - MS
    - Spasticity from Multiple Sclerosis
    - Spinal cord injuries
    - Chemotherapy induced nausea and vomiting
    - Cachexia in HIV/AIDS
    - Cachexia in Cancer
      Chronic neuropathic pain
    - Chronic pain and in conditions including:

      -hyperalgesia
      -post operative pain
      -rheumatism
      -fibromyalgia

    - Epilepsy
    - Glaucoma
    - Tourettes Syndrome
    - Gastrointestinal disorders/diseases
    - Urinary/bladder dysfunction
    - Schizophrenia

These studies promote the use of cannabis as:

- a sleep aid
- an appetite stimulant
- an antiemetic
- a tremor preventative
- a mobility aid
- a muscle relaxant
- an analgesic

In addition, reviews[206] and other scientific reports[207], demonstrate a large number of preclinical and clinical studies, in vivo laboratory studies, in vitro animal studies, case reports, scientific literature and anecdotal evidence, for the use of cannabis in:

- ADHD
- Addiction/withdrawal
- Alzheimer's Disease
- Allergy
- Amyotorpic Lateral Sclerosis (ALS)
- Angiogenesis
- Anorexia Nervosa
- Anti bacteria, viral, fungal, protozoan operations
- Anxiety
- Atherosclerosis
- Arthritis
- Asthma
- Autism
- Cancers:

  -breast cancer
  -prostate cancer
  -colon cancer
  -gastric cancer
  -bladder
  -Kaposi's sarcoma
  -Leukemia
  -neuroblastoma
  -gliomas
  -lung
  -uterus
  -endometrial
  -kidney
  -liver
  -thyroid
  -cervical
  -ovarian
  -oral
  -bile tract
  -lymphoma
  -melanoma
  -multiple myeloma
  -nasopharyngeal

-oral
-pancreatic
-pituitary adenoma
-rhabdomyo sarcoma
-squamous cell carcinoma
-vulvar

- Cardiovascular diseases & disorders
- Celiac Disease
- Chagas Disease
- Chronic Lyme Disease
- Chronic Obstructive Pulmonary Disease
- Chronic traumatic encephalopathy
- Complex Regional Pain Syndrome
- Colitis
- Crohn's Disease
- Cushing's Syndrome
- Cystic Fibrosis
- Depression
- Diabetes
- Dystonia
- Eczema
- Edema
- Elhers-Danlos Syndrome
- Encephalitis
- Encephalomyelitis
- Endometriosis
- Fever/temperature control & regulation
- Flu/Influenza
- Fragile X Syndrome
- Female gynecological disorders
- Fertility
- Hepatitis C
- Huntington's Disease
- Immune system / auto immune disorders
- Inflammation and inflammatory disease
- Lupus Erythematous
- Malaria (cerebral)
- Marfan Syndrome
- Meniere's Syndrome
- Meningitis
- Migraine Headache
- Mitochondrial diseases/dysfunctions
- Myoclonus Diaphragmatic Flutter
- Neurological conditions associated with cognitive function
- Neurogenesis
- Neointima
- Neuromyelitis Optica/Devica's disease
- Osteoporosis

- Obsessive Compulsive Disorder
- Obesity
- Parkinson's Disease
- Pancreatitis / pancreatic disorders
- Periodontal diseases
- Poisoning: Heavy Metals. Organeophosphate, paraquat
- Porphyria
- Post Polio Syndrome
- Post Traumatic Stress Disorder
- Psoriasis
- Pruritus
- Radiation illness/ Radiation Therapy
- Reflex Sympathetic Dystrophy
- Restless Leg Syndrome
- Retinitis Pigmentosa
- Scleroderma
- Sickle cell disease
- Sleep and Sleep Apnea
- Stroke
- Wound healing.

12. Over 110 scientific studies have been published evaluating and promoting the safety and efficacy of cannabinoids in the treatment of a wide range of illness in a population in excess 6,000 patients. By contrast, many FDA/TGA approved pharmaceuticals go through far fewer clinical trials.[208]

13. From the period 2005-2012 approved 188 novel therapeutic agents for 206 indications on the basis of 2 clinical trials, with 74 indications being approved on the basis of a single trial and more than this number granted despite conflicting studies. [209] A scientific review of this matter concluded that the clinical trial evidence used and accepted as a basis for recent approvals, varies widely across indications, ''leading to differing levels of certainty about the risks and benefits of newly approved drugs''.[210]

14. There is no legitimacy therefore, in the suggestions that cannabis is not safe and or will be difficult to prescribe or otherwise regulate simply because of the existence of contrary evidence and or claims, in some of the scientific literature.

15. The primary active compound in the cannabis plant referred to as delta-9-tetrahydrocannabinol, or simply ''THC'' is the cannabinoid responsible for psycho activity, and most of the therapeutic benefits cannabis provides. The effects of this cannabinoid however, can vary according to the quality, potency and quantity of cannabis ingested as well as the metabolism and tolerance levels of the individual. The acknowledged possible side effects of this cannabinoid include: bloodshot eyes, dry mouth, increased appetite, sweating, mild palpitations, sedation and anxiety reduction. With larger or more potent amounts patients may experience euphoria, blurred vision, difficulty concentrating, slower reflex response, low blood pressure or increased heart rate, or hallucinations.[211] With heavy use over a long period of time, a proportion of patients may develop increased tolerance, dependence, and withdrawal symptoms. Patients may also allegedly experience restlessness, anxiety, and mental health issues, however the direction of causality has not been proven.[212]Reviews

under controlled conditions indicate however, that both the frequency of side effects and dependence is low, with one review reporting side effects as ‘’modest” and that dependence is only likely to occur in a ‘’very small proportion of recipients.”[213]Longer term studies have not added to this position.[214]

16. Unless and until the psychotropic element of the plant, THC is activated via subjecting the plant to heat beyond a certain temperature (a process called ‘’decarboxylation”) the plant is largely devoid of any psychotropic effects. Consumed in its raw state or through a cold extraction processes, the cannabinoids, still in their acidic form, are safe to consume in large doses without the potential adverse effects of THC in its activated form.

17. Concern has been expressed with the properties and carcinogens in cannabis when Smoked, however the studies, which evaluate the extent, presence and number of harmful substances in cannabis smoke, are contradictory. The largest study on respiratory health and cannabis has concluded that despite the deleterious substances found in cannabis smoke, evidence of long term lung damage from such is weak.[215] There is no evidence linking cannabis smoke with lung cancer and it has been suggested that anti inflammatory, anti tumoral and immune modulating properties of THC may in fact be responsible for this.[216] The largest study on lung health and cannabis has in fact found, that heavy long-term consumption of cannabis smoke does not affect lung function or deterioration any more than in non-cannabis smokers, and that moderate use of cannabis actually improves lung function.[217] General concerns with respiratory health and the delivery of cannabis, have lessened with the popularity and availability of vaporizing technology, an apparatus which uses heat, not combustion to deliver cannabis vapour to the lungs.

18. There have been occasional incidents of infarction, stroke and other cardiovascular effects, noted in medical literature but it is not a problem noted for most young, healthy users.[218] Heavy cannabis use, especially if smoked with tobacco, may aggravate a pre-existing cardiac condition in the elderly.[219] A 2013 analysis of over 3,800 survivors of a myocardial infarction over an 18 year period, found "no statistically significant association between marijuana use and mortality”[220]

19. Studies show an association between the psychotropic element THC in cannabis and mental illness, especially schizophrenia and psychosis. However, the human mind is complex and the precise cause of schizophrenia whilst thought to be genetic and /or environmental is not known[221]. Currently, there are no studies that show cannabis as the cause of schizophrenia. There is no evidence showing a significant association, let alone causation, between cannabis use, bipolar and anxiety disorders. [222] At best, studies have only been able to show a possible association between cannabis use and a possible triggering of a pre existing propensity towards development of the [Schizophrenia] condition.[223] Other studies suggest a possible association between early onset cannabis use and the development of psychosis later in life[224] but yet again, causality has not been established. Although often suggested as a trigger for psychosis, one study could not find any evidence of hospital admissions involving psychosis and cannabis use.[225] It is also acknowledged that both schizophrenia and psychosis occur in persons who do not use cannabis, and that while cannabis use has increased exponentially over the past 30 years, and with schizophrenia levels stable over the last 20 years, there has been no increase in the incidence of chronic mental health disorders that can be attributed to cannabis use.[226] Recent findings from the Harvard Medical School conclude that familial morbid risk for schizophrenia is most

likely to be the cause of the underlying illness in cannabis users and not cannabis itself, regardless of quantity or frequency of use.[227] Health Canada, in its comprehensive dossier for medical practitioners on cannabis use, report possible psychosis, anxiety and other similar effects as ''rare acute complications'' from cannabis use that ''can be managed with conservative measures.''[228] In fact, studies have shown that cannabis has anti-anxiety effects, can improve mood and reduce depression.[229] Cannabinoids are in fact, neuro-protective, and cannabidiol in the plant attenuates the psychoactive effects of THC. Accordingly, CBD it is now currently being investigated for the treatment of schizophrenia, anxiety and other mental illnesses.

20. Like many other substances with a pharmacological operation in the body, cannabis is reported to be contra indicated in pregnancy[230]. However, a study of children (from three days to one month, followed up at one, four and five years of age) to Jamaican mothers who use cannabis culturally, were found to have no ill effects. In fact the study reported that neonates were more autonomically stable and socially responsive, less irritable, more alert, slept better, had more robust motor and autonomic systems, were less likely to show imbalance of tone, need less assistance to become organized, were better self regulated and were considered more rewarding by their mothers than the control group counterparts.[231] Clearly, more research is required on this matter.

21. Cannabis is less addictive than tobacco, alcohol, barbiturates, amphetamines and heroin,[232] and significant withdrawal symptoms are not generally experienced from ceasing use with cannabis.[233]

22. Common over the counter drug, paracetamol causes over 8,000 overdose toxicity cases in Australia each year.[234] Another popular over the counter medication, NSAIDs hospitalises 100,000 people in the USA annually with gastrointestinal bleeding with 16,500 deaths and such statistics are reported as 'conservative.'[235] However, there have been no documented reports of death resulting from cannabis use in over 5,000 years[236].

23. The Victorian Corner Audrey Jamieson reported at the International Medicine in Addiction Conference in March 2015[237] that prescription drugs involved in 82% of the 384 overdose deaths investigated by the Victorian coroner's court in 2014, were drugs commonly used to address stress, anxiety and sleep disorders. Benzodiazepines, were the most commonly implicated drug, followed by opioids, antidepressants and antipsychotics. Further, the deaths attributed to these prescription drugs were almost double the number of deaths involved in illicit drug use. Professor Nicholas Lintzeris, director of Drug and Alcohol Services at South Eastern Sydney local health district, reported that their widespread abuse meant that the harms they cause were only second to alcohol and were ''significantly greater than harm caused by illicit drugs.''[238] In fact, accidental deaths from prescription medications and in particular opioids are more common in Australia today than death associated with heroin use.[239]

24. According to the Merck Index[240] the lethal dose ("LD") of THC in animal models is: 1270 mg/kg for male rats and 730 mg/kg for female rats from oral consumption in sesame oil, and 42 mg/kg for rats from inhalation.[241] However, dogs and monkeys have found to tolerate higher oral doses of THC of in excess of 3000mg/kg.[242] One estimate of the human lethal dose via intravenous administration is 2100mg per 70kg of body weight[243]. The estimated LD of cannabis otherwise, is thought to be around 1:20,000 or 1:40,000 times the amount of cannabis found in one cannabis cigarette at 0.9 grams. To put this in perspective, this would require a smoker to consume nearly

1,500 lbs. (680 kg) of cannabis within 15 minutes to induce a lethal response.[244] It has been suggested however, that overdose on cannabis in humans may be impossible, as no cannabinoid receptors have been found in the cardiac and respiratory centres[245] and the brain, when over stimulation by cannabinoid compounds produces pregnenolone, a hormone that counteracts their effects.[246] This may explain why, no fatal overdose of cannabis has ever been reported.[247]

25. Drug safety is determined by the "therapeutic ratio" which defines the difference between a therapeutically effective dose and dose capable of inducing adverse effects. The lower the therapeutic ratio, the more toxic and dangerous the drug. Aspirin for example, has a therapeutic ratio of 1:20. Two aspirins are the recommended dose for an adult. 20 times this dose, or 40 aspirins, may cause: death, injury to the digestive system and extensive bleeding. The therapeutic ratio for most prescription drugs is 1:10 or lower. Drugs used to treat patients with glaucoma, multiple sclerosis and cancer are regarded as highly toxic. Antineoplastic drugs have a therapeutic ratio that can fall below 1:1.5 and can result in toxic and lethal reactions, even when the correct dose is used. The therapeutic ratio of cannabis however, like its lethal dose estimate, has been considered to be impossible to quantify because it is so high. It has been stated, "there is no question about its safety. It is one of humanity's oldest medicines, used for thousands of years on millions of people with very little evidence of significant toxic effects. More is known about its adverse effects than about those of most prescription drugs."[248] In fact a review of review [249]twenty three clinical investigations of medical cannabinoid drugs (THC or liquid cannabis extracts) with eight observational studies between 1966-2007, found that there was not a ''higher incidence rate of serious adverse events associated with medical cannabinoid use'' compared to no users over this period of four decades.

26. Consequently, in its natural form it is considered one of the safest therapeutic substances currently known. In fact, in 1988 in the matter of Marijuana Rescheduling Petition Docket No 86-22, U.S. Department of Justice, Drug Enforcement Administration (1988) His Honour, Judge Francis Young, at the end of a lengthy legal process concludes: "Marijuana in its natural form is one of the safest therapeutically active substances known to man". He recommended that medical use of cannabis should be allowed.

27. The safety of cannabis as a modern safe therapeutic agent has long been recognized:

- 1944 The LaGuardia Committee Report[250] viewed as the one of the best reports on any drug for its societal, legal and medical content and its thousands of years on the history of cannabis concluded "The practice of smoking marihuana does not lead to addiction in the medical sense of the word", "The use of marihuana does not lead to morphine or heroin or cocaine addiction, and no effort is made to create a market for those narcotics by stimulating the practice of marihuana smoking," and finally "The publicity concerning the catastrophic effects of marihuana smoking in New York City is unfounded.'' The report concluded that claims that cannabis increases crime and mental illness were unfounded.

- 1968 in a UK Home Office select committee, chaired by Baroness Wootton ("the Wootton Report") on cannabis concluded that it was no more harmful than tobacco or alcohol, and recommended a reduction in penalties for all cannabis offences. [251]

- The Wootton Report recommends cannabis preparations and its derivatives should continue to be available for medical treatment and research purposes.[252]

- 1972 US National National Commission on Marihuana and Drug Abuse, recommended that possession of cannabis and distribution of small amounts without remuneration no longer constitute an offense[253]

- 1972 ''Drug Use in America Problem in Perspective'' report US National Commission on Marihuana and Drug Abuse recommends that cannabis be removed from the Single Convention on Narcotic Drugs (1961), finding it does not pose the same social and public health problems associated with the opiate and coca leaf products. Further recommends that cannabis for personal use be permitted[254]

- 1975: hundreds of Doctors call on US Government to instigate further research on cannabis.[255]

- 1977 The Australian Senate Standing Committee on Social Welfare (the Baume Committee) recommends criminal sanction of possession of cannabis be replaced by fines.[256]

- 1978 New Mexico the first state to make cannabis available for medical use.[257] There are now over 36 states in the USA and eight countries that allow lawful access to cannabis for medicinal use.

- 1978 The New South Wales Joint Parliamentary Committee upon Drugs recommends eliminating criminal sanctions for personal use of cannabis[258]

- 1979 Cannabis Control Policy: A Discussion Paper: Canadian Government Health Protection Branch. Department of Health and National Welfare recommends decriminalisation of cannabis for personal use.[259]

- 1987 USA Merck Manual of Diagnosis and Therapy states, "Cannabis can be used on an episodic but continual basis without evidence of social or psychic dysfunction. In many users the term dependence with its obvious connotations, probably is mis-applied... The chief opposition to the drug rests on a moral and political, and not toxicological foundation".[260]

- 1993: Raymond Kendall, Head of Interpol, calls for decriminalisation of cannabis and 55 British MPs call for the recognition and lawful use of cannabis to treat Multiple Sclerosis.[261]

- 1994: Legislative Options for Cannabis Use in Australia[262] concluded "the cultivation, possession and supply of cannabis remain an offence in all Australian States and Territories (and using it is an offence in most), even though cannabis use is commonplace and little evidence exists that cannabis use causes significant harm when used in small quantities. Australian society experiences more harm, we conclude, from maintaining the prohibition policy than it experiences from the use of the drug."

- 1996: Victorian Premier's Drug Advisory Council Report: Drugs and Our Community concluded that cannabis "does not loom large among drug

problems in terms of observable and measurable harm done to users or to others" and was not a considered a ''gateway drug'' to other harder drugs. [263]

- 1997: The Kaiser Permanente Study (USA) - "Marijuana Use and Mortality" April 1997 in the American Journal of Public Health concludes "Relatively few adverse clinical effects from the chronic use of marijuana have been documented in humans. However, the criminalization of marijuana use may itself be a health hazard, since it may expose the users to violence and criminal activity."[264]

- 1997: The British Medical Association (BMA) recommends and calls for medicinal cannabis in the UK.[265]

- 1997: November 5 : EU Parliament Committee on Civil Liberties suggests that soft drugs (primarily cannabis) should be legalised.[266]

- 1998: University of California (UCLA) School of Medicine's Dr. D.P. Tashkin reported findings of an 8 year study on long-term cannabis smoking reports n Volume 155 of the American Journal of Respiratory and Critical Care Medicine,[267] saying "Findings from the present long-term, follow-up study of heavy, habitual marijuana smokers argue against the concept that continuing heavy use of marijuana is a significant risk factor for the development of chronic lung disease. Neither the continuing nor the intermittent marijuana smokers exhibited any significantly different rates of decline in [lung function] " as compared with those individuals who never smoked marijuana. Researchers added, "No differences were noted between even quite heavy marijuana smoking and non-smoking of marijuana.

- 1998: The Lancet medical journal[268] reports "We say that on the medical evidence available, moderate indulgence in cannabis has little ill-effect on health, and that decisions to ban or legalise cannabis should be based on other considerations."

- 2000: August 15: USA CA: Appeals Court approves marijuana as medicine[269]

- 2000: USA CA: doctors may recommend cannabis.[270]

- 2001: Netherlands government proceeds to put cannabis on prescription.[271]

- 2002: Canadian doctors call for cannabis to be decriminalised.[272]

- 2002: Israeli government approves medicinal cannabis for terminally ill.[273]

The list is extensive and continues.

28. Cannabis however, is not ''harmless''. Some populations have been identified as susceptible for increased risks from cannabis use, such as adolescents[274], pregnant or nursing mother's[275] patients with a family history of mental illness, decreased lung function or who have a history of heart disease or stroke [276]. Like many pharmacological drugs available today, there are not many studies on the interaction between cannabis drugs, herbs and supplements[277]. A general cautionary approach would be required for those patients taking: substances that increase the risk of

bleeding; regulate sugars and or blood pressure or cause drowsiness[278]. However, when used judiciously, the safety profile for cannabis consumption is considered to be very good,[279]and the general adverse effects have been stated to not be unlike those seen with other medications,[280] and comparatively, could be regarded as much safer.

29. This is the current position taken by overseas jurisdictions that have implemented medicinal cannabis schemes. Medicinal cannabis in such jurisdictions is treated in the same manner as other pharmaceutical agents from the perspective that risks and contra indications are identified and managed in patients. Medical Information Sheets outlining such matters, as well as: instructions for use, methods of administration, safety information, side-effects, storage and other matters are provided to patients to further manage risks and promote safe and effective use. Patients receive information pamphlets on medicinal cannabis that are the same as those currently provided with prescription pharmaceuticals in Australia**. [See: Annexure 1]**

30. Finally, it must be emphasised, that many individuals within the CCV do not believe that cannabis should be regulated as registered medicine. It is the view of such individuals that cannabis is first and fore mostly, a botanical herb and a source of food. It is not a pharmacological drug. It cannot be replicated chemically in the manner a pharmaceutical compound can be, as it contains over 400 compounds which work synergistically together, and it's chemistry is complex and not fully understood. Cannabis cannot be distinguished from aloe vera, echinacea, ginkgo, goldenseal, ginseng, garlic or ginger. To attempt to regulate cannabis as a registered medicine or therapeutic good, and treat cannabis as a pharmacological drug, is artificial and without scientific merit. [281]

PART THREE

FORMS APPLICATIONS AND DOSING OF MEDICINAL CANNABIS

FORMS APPLICATIONS AND DOSING OF CANNABIS

1. Cannabis used for therapeutic purposes can be taken in a variety of forms and administered in a variety of ways.

2. The form may be either:

    - Natural phytocannabinoid flowers and products, either raw or activated through basic processing, including: drying and curing, for which safety and purity are ensured through high standards of care in growing in combination with lab-testing each batch. Effective dosage is achieved through tests, which establish the percentage of each cannabinoid and terpenes. Accurate dosage regimes can be prescribed for best therapeutic effect as long as dosage regimes are modified (increased/decreased) in dose quantity, proportionally in response to any change in symptoms. Operations to produce such products are generally inexpensive to establish

    - Natural phytocannabinoid flowers and products, containing cannabinoids that are either raw or ‘’activated’’, which are grown under strictly controlled conditions that constitute good manufacturing process standards, used by pharmaceutical companies to grow, process and manufacture other botanicals. Testing each product for potency and safety is also performed batch to batch, however great measures are taken to ensure that each batch is basically the same as the last batch by producing ‘’standardized’ products (with a scientifically acceptable margin for deviation). These products therefor fit the usual criteria for allopathic medicines, being that they have the same medicinal contents in every batch of the product. Operations to create such products cost millions of dollars to establish. These are known as ‘’standardized pharmaceutical grade” and ‘’research grade’’ phytocannabinoid products.

    - Synthetic pharmaceutical cannabinoid products, which are synthesised, processed and manufactured by a pharmaceutical company using highly specialised patented techniques.

3. Cannabis is consumed in the following forms including the leaves, seeds and flowering tops of the plants in the form of concentrated or extracted resins and oils, or in the for of infused tinctures, lotions, edibles, pills or sprays. These products can be regular medical grade (i.e. potency tested after production) or pharmaceutical grad (i.e. potency standardized during growing and tested after production.

4. The forms involve fresh or dried plant materials, extracted concentrates and infusions which are sometimes prepared without using heat to produce inactivated substances high in THC acid.

5. It is acknowledged that concentration of phytochemicals in the plant will vary due to strain/cultivation, growing, harvesting and processing conditions and techniques. Growers who cultivate and cross breed plants over multi generations, do so in order to refine concentrations of certain properties in the plant that are deemed desirable. Hypothesis for breeding, are often discovered and or tested for, by consuming a mixture of certain products, to identify what the results of breeding might be. In Australia the properties are identified by cottage industry methods and not laboratory testing, due to current laws of prohibition.

6. Currently, potency of the cannabis strain is determined primarily by testing a small dose, which is either consumed orally or inhaled. Potency can also be estimated through smell. As a general rule, the greater the quantity of aromatic terpenes present in the plant, the stronger the plant material usually is in terms of its cannabinoid content. Each strain and product, usually has a distinct bouquet, based on a unique mixture of terpenes that can also be measured through testing. Terpenes are responsible for the flavour and odour when the plant material is burned. Visual appearance is also an indication of potency due to the presence, colour and quantity of the resin producing glands, trichomes, in addition to tactile sensation to determine the presence, quality and quantity of the sticky resinous material secreted by the trichomes.

7. It is acknowledged that some cannabis substances are adulterated with pesticides, chemicals, fertilizers and or heavy metals from the air and soil. Improper harvesting and or curing techniques can produce contamination in the form of: bacteria, mould, fungi and microorganisms. Experienced providers/cultivators of cannabis for medicinal purposes ('compassionate providers") adopt practices and measures which safeguard against these problems, as they are very mindful of the health risks they pose to chronically and or terminally ill patient.

8. Microorganisms associated with botanical products like cannabis, such as the Aspergillus species of mould (associated with respiratory disease) and salmonella muenchen, may not be discernable other than by laboratory testing. [282]

9. With increasing general public awareness on the therapeutic effects of the cannabis plant, there has been a noted increase in the production of substances that are of poor quality and or are not what they are represented to be. Individuals within the CCV are justifiably concerned with this development.

10. As it is unlawful to possess or use cannabis, laboratories will not undertake or provide analysis services to compassionate providers or patients who are currently cultivating and or using medicinal cannabis. Consequently, quality assurance with respect to horticultural, harvesting/curing and storage processes is not presently available.

11. Laboratories in overseas jurisdictions routinely batch test cannabis produced under license by authorized growers and or Compassion Clubs and or Medicinal Cannabis Clinics (dispensaries) that are part of a regulated medicinal cannabis scheme They are able to:

    - identify the compounds in the plant;
    - the percentage of each compound present (i.e. their potency);
    - detect pesticides, fertilizers, heavy metals, chemicals, mould, fungi and microorganisms;
    - assist growers in improving cultivation practices by identifying genetic markers to assist in cultivation; and
    - provide electronic databases with potency and safety test information about products from various different producers (i.e. Co-operatives, Compassion Clubs, Medicinal Cannabis Clinics) and their availability at local outlets.

12. Some laboratories, also operate licenses to grow and dispense cannabis and in addition to the aforementioned services also offer consulting services on regulatory compliance, safety, processing, packaging, labelling and testing methodologies. [283]

13. The suitability of such a model must be questioned. A laboratory that is also a licensed cultivator and dispensary, has an obvious commercial conflict of interest and would not

be viewed as an independent laboratory.

14. Independent accredited laboratories are a more desirable option. Appropriate quality assurance standards and accreditation would ensure consistency in results. This in turn increases patient confidence in the products and assists practitioners in obtaining better therapeutic outcomes.

15. Variation in laboratory results in overseas jurisdictions has been attributed to variations in methodology to testing and equipment used[284]. The following factors will determine the levels of various compounds detected in the plant:

(a) methods of sampling a crop batch[285]:

- details of when it was harvested;
- details of how it was harvested;
- details as to where the sample came from i.e. top of the plant -greater sun exposure-richer compound content -v- bottom of the plant;

(b) how the sample was handled in the laboratory[286]:

- details of how it was stored;
- what methods were used to test and analyse samples;
- age and state of the equipment used: and when was it last calibrated.

16. Methods used to detect plant compounds ("detectors") in cannabis include use of gas chromatography ("GC"), high performance liquid chromatography ("HPLC") and thin layer chromatography ("TLC")

17. Variations in the methods associated with these detectors, also effect the accuracy of results. GC for example, uses a thermal conductivity detector, a flame ionisation detector or mass spectrometer. GC converts the heat sensitive cannabinoid acids, to their activated form. HPLC allows the acid cannabinoids to be quantified separately from the active cannabinoids. TLC on the other hand is limited to limited to detecting specific cannabinoids but cannot detect the quantity or concentration present.[287] For specificity of product and contents, one or more of these methods may need to be employed.

18. It is also important that laboratories operate in a uniform and standard manner to provide confidence in product contents and to assist Medicinal Cannabis Practitioners in achieving better therapeutic outcomes for patients.

19. Consequently, some overseas laboratories have achieved certification and method validation in relation to: their range, ruggedness, method detection limits, extraction efficiency, selectivity and specificity.[288]

20. The information acquired from this process has then been presented by such overseas laboratories, in a format similar to the nutritional profile information found on food packaging, in a clear data table.[289]

21. The information provided by such tests is very useful in assisting patients to select medication choices that are safe and good value for money based on their potency and general profile. They can be assured that higher asking prices for ''superior'' products are justified.

22. Some independent laboratories, such as Steep Hill Halent, in the USA, have also offered add on services to third party cultivators and distributors (i.e. licensed growers, Medicinal Cannabis Clinics/Dispensaries, Co-operatives, Compassion Clubs, manufacturers of edibles etc.) in the form of:

- certified ''safe cannabis'' seals, labels and stickers -for their product to inform their clients;
- certification training and auditing;
- safe seal and packaging program for increased quality control for producers of goods before they reach the market;
- nitrogen filled and tamper proof packaging services to: reduce mould, bacteria, degradation, discolouration, freshness and security for regulatory compliance;
- risk management and regulatory compliance consulting services.[290]

23. The Steep Hill Halent ''safe cannabis'' seal is a guarantee to third parties using and relying on the product that it is pesticide-free, and properly measured for potency.[291]

24. The nitrogen filled and tamper proof packaging and tracking services, guarantees third parties of the safety and quality of the product:

> ''Steep Hill Lab offers nitrogen packaging services for legal medical collective and cooperative growing operations (e.g., those permitted under the Mendocino County 9.31 exemption). The tamper-proof packaging keeps the cannabis as fresh as the day it was sealed, substantially reducing mould and bacterial growth, and significantly reducing degradation and discoloration. To ensure safety, each package includes oxygen and humidity Indicators to show if the package has been tampered with.
>
> Steep Hill makes arrangements with growers to put medical grade cannabis into one-pound bulk mylar packages injected with nitrogen. At the point of packaging Steep Hill collects 4-gram samples for analysis. Each package is labelled with identifying numbers that correspond specifically to samples analysed for quality control. Any product that has unsafe detectable amounts of microbiological contaminants or pesticide residue is rejected. Results are provided within 10 business days.''

The grower can use Steep Hill's Certificate of Analysis results to label their tamper-proof packages of medical grade cannabis. The grower can then distribute the product with the Safe Cannabis seal to dispensaries along with the results log and the information for documenting and validating the analysis. The dispensaries can use the supplied information to contact and validate the authenticity of the Safe Cannabis seal directly with Steep Hill Lab. With the identifying batch and lot numbers on each package, the dispensary can track the results and ensure that the products have been analysed. As a result, the packaging meets the chain of custody requirements linking the contents to lab testing results."

25. It is acknowledged that testing of cannabis and cannabis products under a regulated medicinal cannabis scheme would:

- provide greater consistency in cannabis/cannabis products.
- provide greater certainty to patients as to the content and quality of their cannabinoid medicine.
- would assist patients in selecting price variable cannabis/cannabis products based on their measured contents of medicinal compounds.
- assist in providing and making information available on the labels of products to make it simple to work out appropriate levels of dosing of cannabis/ cannabis products and assist in optimizing therapeutic outcomes.
- assist in providing data that can be made available to patients, doctors/therapeutic practitioners, regulators and scientific researchers on available strains at various licensed distributors and retailers including Compassion Clubs and Medicinal Cannabis Clinics (distributors).
- bring cultivation, manufacturing and processing practices associated with cannabis into line with other similar regulated industries, legitimizing the cottage industry.
- Optimize horticultural and cultivation techniques and advance scientific knowledge in these areas.
- promote greater confidence for patients, doctors and or other therapeutic practitioners, as well as the general public in the products and their use with a medicinal cannabis scheme.

26. Patient's access to cannabis under any regulated scheme is vital to its success. If patients are unable to practically access cannabis, they will not embrace the system and return to buying their medicine from the illicit market.

27. Cost is a key consideration to accessibility. Whilst it is acknowledged that laboratory testing and analysis of cannabis/cannabis plants may be necessary, it is understood that this will contribute to the production costs of the final product. It is suggested, that the costs associated with any laboratory testing (direct or indirect) should, under a compassionate scheme, be paid for by the Victorian Government out of licensing and taxation revenues raised from any proposed scheme.

28. It is submitted that lawful access to specially accredited government and or commercial laboratories by third parties such as: licensed cultivators, Medicinal Cannabis Clinics/Dispensaries, Compassion Clubs / Co-operatives, and patients is both desirable and necessary and that testing of cannabis for safety concerns and potency should be mandatory where it is distributed to third parties or commercially, as opposed to self /home grow operations for personal use, where the quality is assured and the potency assessed by the patient directly.

FORMS & APPLICATIONS

1. Cannabis therapeutics come in a variety of forms and can be sued via various methods of administration. These include using the natural raw plant materials directly using extracted concentrates or processing the plant materials or concentrates into infused substances, such as tinctures and foods. Processing may result in a variety of activated or inactivated therapeutic products, varying in their chemical composition and potency and therefore in their overall medicinal effects.

2. When cannabis is exposed to heat at or above a certain temperature, this process, known as ‘‘decarboxylation’’, transforms the non-psychotropic cannabinoid THCa into the psychotropic form THC –delta-9 by removing the carboxyl group of molecules. THC-delta-9 can be further processed to produce THC-acetate, which improves its water solubility and allows it to cross the blood-brain barrier more effectively assisting them to pass across the blood/brain barrier. This can also vary its effects, as well as extending its period of operation.

3. These forms of therapeutic are referred to as ‘’activated’’ substances. These substances are extremely effective for treating a large variety of illnesses, but require a little more care and attention to dose and or method of application, which are determined according to an individual's ailments, needs, age, composition of the substance (strains of plants selected for example sedating strains–v- activating strains), potency or the ratio of THC to CBD (as CBD counteracts the effectiveness of THC) all of which are easy to identify, address and manage under a regulated system.

4. The forms of therapeutics do vary in their constituents and compositions.

5. Activated forms may lose many of the important but delicate terpenes, which evaporate at lower temperatures than is required for decarboxylation of cannabinoids. This can be avoided by curing flowers over time in an airtight container.

6. Some activated therapeutics are more intoxicatingly potent than others. For example, concentrated extractions such as oil, ‘’wax’’ and ‘’shatter’’ are more potent, more easily to titrate their dose and more effective medicinally than other forms, particularly through inhalation i.e. smoking/vaporizing, often used for rapid relief of acute symptoms.

7. Different forms of cannabis therapeutics, also deliver different quantities of cannabinoids to the body. For example, smoking/vaporizing delivers more cannabinoids more quickly than some other methods, but oral use (i.e. tinctures and infused edibles) provide sustained medicated levels over a more extensive period and for this reason different products and methods of administration are often used in combination with each other.

8. The form and method of administration, will also affect the rate of medication onset. Some forms are much quicker than others i.e.: smoking/vaporizing produce quicker symptom management for some ailments than do other forms i.e. infused edibles/tinctures and orally administered oils, that can take up to an hour or more to reach full effect. However, when applied to the gums cannabinoids enter the bloodstream via a trans-mucosal process with much faster onset, as do suppositories containing cannabis oil, which by passes the stomach. Suppositories may also be used for patients who have difficulty swallowing or ingesting food. Selecting the form(s) and modes of delivery, is dependent upon an individual’s condition, lifestyle and ability to tolerate and manage any effects of activated forms.

9. The percentage of THC present may vary depending on strain used and from batch to batch of plant material due to growing/harvesting conditions. For example, the tops of the flower and their position on the plant (with those at the top exposed to more sunlight and are therefore more likely to have slightly higher levels of THC than those flowers lower on the plant or obscured from light). Laboratory analysis and quality controls under a regulated system are used to address these concerns in overseas jurisdictions that operate legal regulated Medicinal Cannabis Dispensaries.

10. The versatility in the forms of cannabis therapeutics and their applications allow great flexibility and enhanced clinical outcomes.

11. Juicing Cannabis: cannabis juice is derived from the whole cannabis plant and juiced in the same manner that fruit and vegetables are.

12. Dried plant material: consists of flowers and leaves dried to prevent degradation and preserve the desired properties in the plant. As flowering buds of the female plant hold the highest concentration of cannabinoids, these are specifically sought and used for therapeutic purposes.

13. Dried plant material can be used directly (i.e. smoked or vaporized) or with further processing, to produce extracts, concentrates, food and drinks.

14. Using dried plant material is easy and versatile, to use as noted and employed by the Office of Medicinal Cannabis in the Netherlands.[292]

15. Dried plant material can be used to make infused substances using both hot (activation of THC or simply ‘’activated’’) and cold processing methods (non activation of THC or simply ‘’inactivated.”). When it is not smoked, for example, ingested raw or processed in non baked food’s, it produces a non activated medicinal.

16. As cannabinoids are lipophilic in nature, the process to produce infused substances involves submerging plant matter into a base of oil or solvents where cannabinoids and other compounds in the plant are transferred into the oil or solvent base. The process involves mixing plant material with cocoa butter, dairy butter, cooking oil, coconut oil, glycerine or a skin moisturizer (for topical use). These infused substances can be consumed neat or put into gel caps and used orally, as a suppository, applied directly to the skin topically or used in drinks and foods.

17. Cold extraction using raw or dried plant material is not subjected to heat and is therefore not decarboxylated, which fails to activate THC. The process is popular, because it is effective, clean, safe and easy. Those concerned with the possible undesired effects of THC find this processing method and end substances popular, however the medicinal effects of these products are different to those with activated THC.

18. Non activated formulations include: raw undried, leaves and uncured flowers,‘’Kief’’ (trichomes): rubbed or shaken from the living plant. Although it can also be smoked and found in baked edibles, it can also be ingested raw. [293]

19. **Hash:** Hashish is a concentrated resin cake or ball produced from pressed Kief, of trichomes that have fallen from the plant or alternatively, from scraping the resin from the surface of the plant and rolling it into balls, blocks or sheets. Hash is produced by cold water and ice extraction method. Although the end product is popular to smoke, vaporize and use in cooking, it can also be ingested raw.[294].

20. **Hash Oil / and Wax** is a resinous mix of plant properties using solvents such as Co2, OX or butane. [295]to form various hardened or viscous masses. Solvents are removed through a cold extraction or heat evaporative process. Although Hash Oil/wax can be burned, and is popular to use vaporized, and in edibles, it can also be ingested raw and used in salves or skin preparations. When it is vaporized at low temperatures, ingested raw or processed in non baked foods, it is a non-activated substance.

21. **Oil:** a cold extraction process involving plant material soaked in coconut or olive oil. It can be taken neat or added to food.

22. **Tincture**: the cannabis is bathed and left to sit in alcohol, which extracts the properties from the plant. The alcohol containing the plants properties is filtered from the plant material and used orally, or in food and drink.

23. Heated extractions/concentrates convert the cannabinoid acids from their neutral forms, activating THC.

24. Activated products include:

- Tea: extracted and placed into hot water and drunk;
- Tincture: cannabis is subjected to heat to decarboxylate the cannabis (activate THCa into THC) and the plants properties are extracted using an alcohol base and administered orally under the tongue or added to food and drink;
- Oil: cannabis is subjected to heat (to decarboxylate the cannabis -activate THCa into THC) and transferred into a lipid such as coconut oil, olive oil, dairy or coco butter, or glycerine, to extract properties from the plant. Used neat orally or placed in gel caps, as suppositories, topically or added to food;
- Butter: cannabis infused with butter over heat, with the oil containing the plants properties, extracted from the plant material. Used orally and or in foods;
- Salve/cream/lotion: low heating of cannabis with beeswax. Used topically;
- Smoking & Vaporizing Kief, Hash, Hash Oil/Wax.

25. Applications and administration routes for both activated and inactivated substances are oral (smoking, vaporizing, drinks and edibles), topical and suppository.

26. It is the view of many Medicinal Cannabis Practitioners in overseas jurisdictions that inactivated substances, are relatively safe to use for medicinal purposes.

27. Pharmaceutical grade cannabis includes: Dronabinol (marketed as “Marinol”) – is a synthetic THC. It has been approved for nausea and vomiting in chemotherapy patients and weight loss in AIDs. It is an oral capsule. Nabilone –(marketed as “Cesamet”) is also a synthetic of THC, approved for use in chemotherapy-induced nausea and vomiting. It is taken orally in capsule form. Nabiximols – (marketed as “Sativex”) is a 1:1 ratio of THC and CBD from the cannabis plants, approved for spasticity in patients with multiple sclerosis. It is an oral spray. Nabiximol is the only pharmaceutical cannabis product currently approved for use in Australia. It was only very recently scheduled as a controlled drug (SUSMP Sch 8) to be made available on prescription for use in multiple sclerosis.

28. In several medical studies, the effect of THC and pharmaceutical grade products like Marinol alone, could not match the effect of total cannabis preparations, Indicating that there might be other active cannabinoids needed for a full range of therapeutic effect[296]

29. Whole plant therapy contains a wide spectrum of modulating and synergistic effects. Pharmacological grade cannabis products are extractions of one or two cannabinoids (THC and or CBD) of the plant. Their concentration is at the expense of the entourage effect and the synergism that operates between the various compounds.

30. Aside from cannabinoids identified in this paper, there are still many yet to be discovered and understood. To extract a few cannabinoids from the plant in these circumstances and promote it for therapeutic purposes is premature.

31. Whilst it is acknowledged that pharmacological cannabis products may serve some patients needs, the CCV advocates the use of whole natural cannabis medicine, which may be accessed in the following forms.

COLD EXTRACTION PROCESS: INACTIVATED THERAPEUTICS

JUICING CANNABIS

1. Juicing Cannabis: Cannabis juice is derived from the whole cannabis plant, which is, juiced in its raw state in the same manner that other fruit and vegetables are juiced. It is considered a safe and highly effective means of delivering the acidic-cannabinoids and all other properties of the plant to the body. The entourage effect of the plant is promoted, (albeit largely without the activated cannabinoids including THC and CBD) without loss of any of the plants phytochemicals. This enables the synergistic application between properties to bring the body back into a state of homeostasis. Dr William Courtney in the USA, who studies and successfully treats patients using cannabis juice, believes it a safe and more effective method than consuming some other forms of cannabis for their therapeutic benefit. As it is an inactivated form of therapy, juicing the plant material (leaves and stems) enables a patient to consume higher quantities of cannabinoids than a patient might otherwise be able to tolerate or manage if they were activated.

2. In Canada, juicing has become an increasingly popular method of cannabinoid therapy[297] 20 leaves a day is recommended for juicing purposes and strain of plant is matched according to a patient's symptoms/disease and dose can be titrated. Unless home grown, plant material is subjected to laboratory analysis to ensure it is free of harmful substances and to provide a chemical profile of the plant, which measures the percentage, and hence the milligrams of desired properties within the plant material to be used, so that accurate dosing regimes can be established.

3. It is submitted that:

   - juicing is a nutritious safe whole plant therapy;
   - it is superior to some alternative forms of cannabis administration as it preserves all the photo chemicals in the plant which work synergistically together within the human endocannabinoid system;
   - it is a desired option for patients and health practitioners seeking to work with the entourage effect of the whole plant;
   - dose can be easily managed and controlled;
   - it is an option for non smokers, person with an aversion to, medical sensitivity,

intolerance or inability to be in the presence of or who wish to cut down on supplemental or inhaled smoke or vapour and/or activated tinctures and edible products;

- inhale smoke or vapour;
- it is a necessary option for those who cannot consume lipid, oil, alcohol in the form of oils, tinctures and or edibles due to dietary or associated health issues;
- it is a clean and discrete therapeutic method;
- it is a highly desired option, especially for those who wish to grow their own medicine; and
- regulation would address quality of product, constituency of the product: (i.e. THC acids, CBD, CBD acid etc.) content, mould, bacteria, chemicals together with potency/serving size/dose quantities, labelling, tamper proof packaging, styling (to differentiate from other products), with any relevant warnings.

Juicing of medicinal cannabis must be made available to Victorian patients under any proposed medicinal cannabis scheme. To exclude this as an option, will deny some patients access to a therapeutic to alleviate suffering and or improve their quality of life.

COLD EXTRACTED CANNABIS TINCTURES

1. Tinctures: cold extracted tinctures produces an inactivated substance involving soaking fresh dry plant material, mostly flowers, but sometimes also leaves and or stems in ethanol, which is then strained to remove plant material and is also used as a carrier. Where desired, the food grade glycerine can be used.
2. It is generally taken under the tongue and absorbed through the mucosal lining where it passes quickly into the bloodstream. A starting dose of not more than a few drops is recommended, waiting for one to two hours before increasing the dose, in order to assess the effects before repeating and or increasing the dose.[298] Its effects are felt within 5 minutes up to 1 hour and last around about 4 hours. [299]Alcohol based tinctures are nearly as old as pharmacy itself, and are commonly associated with herbal preparations and sold as over the counter products. Until the laws of prohibition were introduced in the 1960s, cannabis based tinctures were popular forms of administering cannabis therapeutically in Australia[300].
3. Patients, both in Australia and abroad are reporting remarkable results using quality tinctures [301] with no adverse incidents having currently been noted or reported. Inactivated tinctures are used as a stand alone therapeutic and or in combination with other cannabis substances. As an inactivated substance, ensuring accurate titration of dose to avoid possible undesired side effects of THC, is not problematic, though storage of the products in a cold dark pace is necessary as a precautionary measure to remove the possibility of accidental activation.
4. It is submitted that cold extracted tinctures can be:
    - a safe and effective whole plant therapy;[302].
    - safe and easy to make;
    - easy for patients to administer accurate titration of dosage;
    - superior to some alternative cannabis substances as it preserves all the photo chemicals in the plant that synergistically work together in the human

endocannabinoid system;

- desired for those seeking the entourage effect of acid elements of the plant;
- necessary for those who wish to avoid or are concerned with possible undesired effects of activated THC alternatives;
- desirable option for children and for adults who's circumstances do not require activated / THC substances;
- an important option for non smokers, person with an aversion, medical sensitivity, intolerance or inability to be in the presence of or who wish to cut down on supplemental or inhaled smoke or vapour and/or activated tinctures and edible products;
- necessary options for those who cannot consume lipids (i.e. oil or fats), ethanol or other edibles products due to dietary or associated health issues;
- clean, readily accessible and discrete therapeutic choices;
- regulation would address manufacturing, quality control and testing to establish the composition of products in terms of cannabinoids (i.e. THC acid, THC, CBD acid, CBD etc.) profile. This would allow establishment of dose quantities and safety testing to establish the absence of contaminants such as mould, bacteria, heavy metals, pesticides and other chemicals. It would also establish guidelines for labelling requirements, tamper proof packaging and styling (to differentiate it from standard food products) with any relevant warnings.

Inactivated tinctures of medicinal cannabis must be made available to Victorian patients under any proposed medicinal cannabis scheme. To exclude this as an option, will deny some patients access to an important therapeutic to alleviate suffering and or improve their quality of life.

COLD EXTRACTED CANNABIS EXTRACTS

1. Cannabis Oil: can also be cold extracted to a concentrated form by an extrusion or cold press technique in the absence of light and heat. These extracts can be administered neat or added to cool food, producing an inactivated medicine.
2. Acid cannabinoids are fat-soluble and will dissolve in oils, butters, fats and alcohol, but not water. Processes using oil, butter, or fat can extract the cannabinoids from plant material. Plant material is crushed up and soaked in the oil to extract the plants properties, before it is strained and used orally (neat or with and or in food), topically or as a suppository.
3. It is a popular choice to give to children or for patients who:
    - wish to avoid the use of alcohol; and
    - do not wish to deal with the sedative or other effects of THC.
4. As THC plays a significant role in its operation with other cannabinoids in the plant to bring about homeostasis, cold extracted oils are, also used alongside other activated cannabis medicines, when tolerated.
5. Further discussion on cannabis oils: See Concentrates: Hash and Hash Oil/Wax [below]
6. It is submitted that cold extracted cannabis oils can be:

- a safe and effective whole plant therapy;.[303]
- safe and easy to produce;
- easy to administer required dose;
- superior to some alternative cannabis substances as it preserves all the photo chemicals in the plant that synergistically work together in the human endocannabinoid system;
- a desired option for patients and health practitioners seeking to work with the entourage effect of the plant;
- a highly desirable option for children and or persons who do not wish to activated / THC substances;
- an important option for non smokers, person with an aversion, medical sensitivity, intolerance or inability to be in the presence of or who wish to cut down on supplemental or inhaled smoke or vapour, as well as tinctures or edibles;
- a necessary option for those who wish to utilise acidic cannabinoids but who cannot or do not wish to consume ethanol;
- a clean, readily accessible and discreet therapeutic choices; and.
- regulation would address manufacturing issues, quality of product, constituency of the cannabis: THC:CBD content, mould, bacteria, chemicals together with potency/serving size/dose quantities, labelling, tamper proof packaging, styling (to differentiate from other products), with any relevant warnings.

Cold extractions are a very popular form of medicinal cannabis and must be made available to Victorian patients under any proposed medicinal cannabis scheme. To exclude this as an option, will deny some patients access to a therapeutic to alleviate suffering and or improve their quality of life.

EXTRACTIONS & APPLICATIONS USING HEAT: ACTIVATED THERAPEUTICS

SMOKING

1. Dried flower is used when smoking cannabis. Most flowers retain some degree of acidic cannabinoids. However the heating process, either during decarboxylation or when being smoked or vaporised, produces activated cannabinoids.
2. Using dried leaf or flower involved inhaling cannabis smoke using devices from small pipes or bongs (like a hookah with a water chamber) paper wrapped joints or tobacco leaf wrapped blunts.[304] Although a popular recreational method of obtaining therapeutic benefits associated with cannabis, this method has been found to be relatively safe, though long term use is rare.[305]
3. Prolonged and deeper inhalation methods are involved to deliver THC and other properties to the lungs and then other tissues of the body. The method provides rapid onset of the effects of THC compared to other methods. [306] 40-70% of THC has been detected in cannabis smoke in a number of studies, [307] though only 5- 24 per cent of THC is said to reach the bloodstream in this process.
4. Smoking cannabis has raised concerns regarding pulmonary health. Though on balance, it appears that it constitutes in some people, some respiratory irritation.
5. Harmful chemicals similar to those found in tobacco smoke have been found in the smoke of cannabis. The substances include bronchial irritants and carcinogens[308] with three times the tar content of cigarettes, five times the carbon monoxide concentration, together with higher levels of ammonia and hydrogen cyanide.[309] However, other studies report contrary findings and some suggesting that other constituents (polonium-210, lead, arsenic, nicotine, and tobacco-specific nitrosamines) are lower or do not exist at all.[310] Associations between lung disease, tobacco and the use of chemical fertilisers have also been noted[311]. Organically grown medicinal cannabis is currently supplied to many patients in need in Victoria, by compassionate care suppliers.
6. Whilst there has been some association between respiratory irritation and cannabis smoke (increase in cough, sputum production, airway inflammation, and wheeze) it has been stated that this finding is similar to the findings associated with tobacco smoking[312].
7. Studies looking at Bullous lung disease (abnormal airspaces in the lungs due to damage in the lung wall) and pneumothorax or collapsed lung conditions, have failed to definitively link, cannabis smoke to these conditions.[313]
8. Some studies with negative findings, have failed to exclude those who are also frequent tobacco users [314] or failed to account for other potential factors such as lifestyle, impacting outcomes. Existing laws on prohibition have also presented difficulties for illicit users and scientists in having access to quality ‘’standardized’’ research grade cannabis, free of contaminants and additives. These factors must also be acknowledged in study outcomes.
9. Despite the presence of bronchial irritants, chemical and carcinogens found in cannabis smoke, an association between cannabis smoke and cancer, has not been demonstrated.
10. A systematic review of the medical literature has failed to find a significant association between smoking cannabis and lung cancer, after adjusting for tobacco use. [315]
11. Lung biopsies from habitual cannabis smokers have failed to find cancer, even though

alteration to tissue some of which were recognized, as precursors to the development of cancer were present. [316]

12. Heavy cannabis smokers (> 20,000 joints over their life) do not have an increased risk of lung cancer[317]. A twenty fold increased risk of lung cancer has been found in those smoking two or more packs of cigarettes a day consistent with other studies [318] confirming that the more tobacco consumed, the greater the risk for developing, lung, head and neck cancers. [319]Mixing cannabis with tobacco has the same risks associated with the use of tobacco alone, however cannabinoids recognised for their anti cancer properties, go a long way towards mitigating or eliminating the carcinogenic potential associated with smoking tobacco.

13. It has been suggested[320] that the reasons for these findings is that THC in cannabis smoke promotes apoptosis, counters angiogenesis, associated with cancer growth and progression and is a strong antioxidant. This is consistent with others studies that have reported that long term cannabis smokers are 62% less likely to develop head and neck squamous carcinoma than non smokers. [321]

14. The aforementioned findings were the result of the largest study cohort on respiratory health in cannabis patients who were studied over a 20 year period. This study[322] also found:

    (i) that moderate cannabis smokers enjoy improved lung function over non-users, and that heavy users demonstrate the same lung capacity and /or deterioration as non-users;

    (ii) evidence of long term damage to the lungs from cannabis smoke, despite its noted deleterious properties to the respiratory system, is weak;

    (iii). anti inflammatory, immune suppressing properties and anti neoplastic effects of THC are likely to preclude the development of pulmonary diseases and cancers.

    It can be concluded that:

    - minor irritation caused by smoking cannabis is no different from or to cigarette smoking;
    - long term heavy use of smoking cannabis is rare;
    - risks of other pulmonary lung diseases is not evident over long term, medium to high use;
    - benefits from moderate use in the form of improved lung capacity are evident;
    - long term use of smoking cannabis is rare, and the trend in overseas countries suggests it will continue, with the introduction of new vaporizing technologies, together with non-polar extracts specifically designed for vaporisation including BH) and CO2 oil, as well as waxes (oil made solid through a vacuum process) and refined (known as ‘’winterized’’) ‘’absolutes’’(aka ‘’shatters’’ that have undergone a further refinement process to remove waxes) which contain less irritants than plant matter;
    - THC may provide protection from pulmonary diseases;
    - Rapid onset of the effects of THC provide immediate re-address for and relief of symptoms and used primarily by medicinal users for this purpose; and
    - Only 5-24 per cent of THC reaching the bloodstream enables medicinal users to titrate their dose gradually, until they experience relief of their symptoms .In this respect, dosage can be reasonably controlled similar to therapeutic doses of pharmacological drugs in a clinical setting, which are often adjusted to address

unpleasant side effects and provide symptom relief.

15. A study by McGill University USA in 2010 found that smoking cannabis significantly improved pain, sleep quality and anxiety in patients for whom Conventional treatments had failed. [323]

In 2013, the University of California Centre for Medicinal Cannabis Research conducted a series of randomized placebo controlled clinical trials, on the medical utility of inhaled cannabis, which adhered to the ''gold standard'' FDA protocol for clinical trial design. These studies conclude that cannabis should be "a first line treatment"" for patients with neuropathy and other serious illnesses.[324]

The view expressed by the Commission at 2.31 that with the exception of the terminally ill, a ''significant percentage of patients'' reject this as a medically acceptable model, is questioned for the following reasons:

- recreational usage of cannabis smoking is relatively high in the population and has increased exponentially, despite no documented increase in serious disease;

- recreational or one time recreational users are and also become patients and smoking is the method of administration they are familiar with and achieve a dose related response from: and

- non-cannabis smokers, who become patients, also comprise of those who consume tobacco.

16. Smoking cannabis is popular with patients as a means of addressing acute symptom management. A study on medicinal cannabis users in 2011 showed that smoking cannabis was in fact the preferred method of administration over all others, including vaporization. 67% of respondents stated that they preferred this method. Fast acting, immediate results and ease of dose titration were suggested as the reasons for these findings.[325]

17. Dose is titrated with a puff and a wait period of minutes (5- 20 min) is allowed to determine the effects, before continuing. Small shallow inhalations are recommended and holding the smoke is not necessary, as studies show that 95% of the THC is absorbed in the first few seconds of inhalation.[326] It is thus easy for patients to control their dose and manage symptom relief accordingly. Oral pharmaceutical THC preparations (dronabinol, Marinol, nabilone, Cesametr) by contrast, can be problematic for patients, as absorption of these substances is from the stomach and is much slower, with peak dose concentrations occurring anywhere between 1-6 hours after a dose. This results in delayed onset reactions with no ability to attenuate the effects. Further, compared to smoking, bioavailability of these products range between 5-20% per dose with a magnitude of approximately 10% of that achieved from smoking.[327]

18. The average dose identified in a number of studies, is between 1-3 grams smoked or vaporized cannabis daily.[328] A recent Canadian study found 25mg of cannabis with THC content of 9.4% as a single inhalation three times daily for a 5 day period was well tolerated and effective in reducing pain and improving sleep. [329]

19. If patients choosing to smoke cannabis in a rolled joint, overseas medicinal cannabis centres (dispensaries) and Compassion Clubs do not promote the use of rolling cannabis with tobacco, but rather with other herbs such as: damiana, coltsfoot, mullein, and peppermint.[330]

20. Pipes can be used as an alternative to avoid smoking paper, and water pipes made of

glass are preferred to prevent ingestion of other potentially harmful substances, that can potentially be created when cannabis is burned in metal.[331]

21. It is submitted that:

- the risks of smoking cannabis are less than those associated with tobacco, with direct benefit of improved pulmonary function with moderate users;
- smoking is an expedient method to provide relief from acute debilitating symptoms;
- dose is easily managed and titrated by the user, with effectiveness being addressed via appropriate plant strain selection i.e. higher or lower ratios of THC in the plant;
- immediacy of effect offered by smoking and the control offered by titration, are safer forms of medicating than oral pharmacological alternatives with standardized doses and delayed onset effects from 1-6 hours;
- smoking is accessible and more cost effective than some alternative forms and application methods which may involve expensive delivery device i.e. vaporizers;
- smoking is convenient and does not rely on having to access delivery apparatus;
- smoking is more widely available and accessible than some other forms that may require acquisition of knowledge in their preparation and use;
- smoking may be preferred by those who cannot consume ethanol (tinctures) and or lipids found in edibles or have other dietary or associated health issues commonly associated with food i.e. allergies, sensitivities;
- high use employing this application of cannabis, over the long term is rare;
- smoking is not a suitable option for children; and
- regulation would address manufacturing issues, quality of product, constituency of the product: THC:CBD content, mould, bacteria, chemicals together with potency/serving size/dose quantities, labelling, tamper proof packaging, styling (to differentiate from other products), with any relevant warnings.

Smoking cannabis is an efficient, effective, practical and accessible method of THC delivery to the human endocannabinoid system. It has been a popular form of medicinal use for many centuries, undoubtedly for these reasons. It addresses multiple patient needs and must therefore be included as an option for use, in any proposed medicinal cannabis scheme. To exclude this as an option, will deny some patients access to a therapeutic to alleviate suffering and or improve their quality of life.

CONCENTRATES

. Concentrates involve an extraction process using solvents to produce concentrated forms of activated medicines.

HASH and HASH OIL/WAX

1. **Hash:** is a collection of the resinous trichomes from the flowers, which have been separated. “Pressed hashish’’ is made using various grades of mesh screens to separate the dried, cured plant material from the trichomes, and then pressing the loose

trichome dust together under heat. The more heat and pressure, the more the trichomes burst and form a solid mass, which changes the chemical composition. Hashish from Morocco and other countries is generally made using this technique but it is also used in the Netherlands and North America.

2. **Hand rubbed hashish** ("Charas"): is produced by rubbing live plants during their growing cycle, which is mostly acidic cannadinoids until it has cured some months. Consuming hand rubbed hashish is usually higher in TCH than pressed hash so produces a more cerebral effect when consumed.

3. **Water-hash or ''Bubble" or "Ice" hash:** is separated from the plant matter using ice, water and varying grades of mesh bags to produce products of graduated purity. The fines grad of water-hash is called ''full melt'' hashish and is very pure and capable of providing strong medicinal effects through very small doses.

4. **Hash oil** (to be distinguished from hemp seed oil): is a resinous mix of the cannabis plant's active properties in varying levels of purity, created using:

   (i) ''polar solvents'' such as ethanol, glycerine and isyproply alcohol;

   (ii) ''non-polar solvents'' such as:

   - Co2, butane or naphtha/hexane; or
   - simple coconut or olive oil draw;

   to draw out the cannabinoids and other properties in the plant.

5. Polar solvents produce "full plant extracts" that are dark in colour because they contain chlorophyll. An example of such is "Rick Simpson Oils" Polar ''whole plant'' extracts such as "Rick Simpson's Oil" or "RSO's are usually made with ethanol or isopropyl alcohol extraction and contain all the active components of the plant plus chlorophyll and waxes. If used for inhalation purposes, these can irritate the throat when inhaled. They are primarily ingested and are not helpful for treating acute onset symptoms because of their delayed operation due to the digestive process.

6. Non polar solvents produce ''non-polar" extracts that are light in colour due to their lack of chlorophyll and are known as Butane Honey Oil ("BHO") or Co2 Oil depending on the extraction solvent used. These substances are what the aromatherapy industry calls ''concentrates''.

7. Both polar and non polar extraction processes will use decarboxylation prior to and or during the extraction process to produce an activated therapeutic. In doing so, these products much of the aromatic terpenes, that are thought may play a contributing role to the modulation of THC, are lost in the evaporative process. This has resulted in the creation of new technique where ''live resin'' is extracted from fresh flowers that have not been decarboxylated, to produce oils that pungent, flavourful and high priced, but which do not produce as much activated THC in the final product in contrast to products made from dried, cured flowers.

8. Non polar extracts can also be:

   - treated (''purged'') under pressure using a vacuum chamber to produce a stable

at room temperature substance known as **''wax''** that is easier to administer by vaporization and reduces wastage, associated with sticky and messy oils;

- refined further, to remove some of the remaining (polar) plant matter (mostly plant waxes) by undergoing a subsequent polar-wash (i.e. with alcohol) and ''winterisation" (paced in freezer for 48 hours to coagulate the plant waxes, and then strained) to produce, what the aromatherapy industry call **''absolutes.''** These products are what the cannabis community calls **''snap-and-pull''** or ''**shatter''** due to their semi hard to hard crumbly consistency.

9. With professional distillation equipment, concentrates can be extracted and or refined further. Extraction and further refinement, is undertaken primarily for the purposes of inhalation, to reduce plant matter that can cause irritation to a patients respiratory system. However, the equipment required to do this, is largely inaccessible to most cottage industry operators in Australia.

10. Extracts can also be further processed or refined using an acid based extraction technique, which requires a basic knowledge and understanding of chemistry, to create extracts that are almost completely pure cannabinoid mixtures with almost no polar impurities. These are the most potent and expensive cannabis medicines available today.

11. Concentrates and extracts are cleaner, almost odourless method of administering cannabis, which can ensure greater accuracy of dose titration than cannabis flower, as their content is homogenous.

12. As a concentrated source of the plants properties, they have higher potency, so smaller therapeutic quantities are required and higher doses can be administered much more quickly, which makes it a productive and more efficient means of delivering fast symptom relief.

13. Concentrations of the resinous trichomes, like hashish, come in various grades from various strains of plants, types of flowers, harvesting and processing techniques.

14. Hashish can range from 3% (i.e. low grade Moroccan hash) to around 85% THC (i.e. modern "full melt" hash created with ice water and incredibly fine sieves to filter out almost all of the plant matter). Extractions such as Rick Simpson Oil (also known as RSO whole-plant extracts), Co2 extracts, and BHO extracts range from around 60% up to 99% THC, depending upon the variables and extraction methods used.

15. There is disparity on how potent concentrates are and the literature is not consistent on the matter with variations of 10-30% THC by weight[332], to 20-65%[333] .The UN Office On Drugs and Crime guidelines regarding cannabis state[334] that:

    "The THC content of the different cannabis products (herb, resin and oil) is the result of the ratio of the different plant parts used in their production. A study in Switzerland in 2006 showed, for example, that two thirds of seizures of herbal cannabis ranged between 2 per cent and 12 per cent THC. Two thirds of the resin seizures ranged between 4 per cent and 21 per cent, depending on details of the cultivation and production method (see also chapter 3.13.2), while extraction of resin and/or flowering tops can result in cannabis oil with a THC content of up to 60 per cent."

16. Overseas jurisdictions that dispense these products, report potency ranges from 60-85%, with slight variation outside this range. [335]

17. Hash oil is consumed via ingestion, smoking or vaporizing (sometimes referred to as

''dabbing'')[336], as well as topically and or in suppository form.

18. The advantages of non-polar Co2 and BHO extracts are:

- they are clean and have little odor;
- they do not contain chlorophyll and plant waxes which can irritate the respiratory system and so, are much easier to inhale than polar 'whole plant'' extracts;
- their purity and higher potency means that smaller therapeutic quantities are required;
- higher does can be administered easily and quickly when required; and
- their consistent potency allows for easy dosage, control and titration.

19. These products are both convenient and assist a patient with maintaining accurate dosing. More importantly, they deliver fast relief for symptoms and this can be critical with acute onset symptoms that may be life threatening, such as seizures. For these patients, inhaling enough cannabinoids from a vaporiser or joint containing flowers could take minutes to prepare and consume, which cannot be easily managed during a panic attack, epileptic seizure or similar medical event. Inhaling cannabinoids at the push of a button through a tiny dab of extract in a "dab-pen" takes just moments. For many patients the difference can mean the difference between life and death.

20. Concentrates made using various solvents should be completely purged through an evaporative process, to leave behind concentrated oil. Where solvent chemicals are not flushed from the extract, they may, in some patients, create unwanted toxic effects and symptoms. This issue can be mitigated by using ''clean'' solvents and purging completely (ideally using a vacuum oven, or vacuum chamber and electric heat pad). Such products supplied to third parties should therefore be subject to mandatory ''residual solvent'' testing by accredited laboratories.

21. Producing hash oil products involving, Co2, or butane, with flammable solvents also carries the risk of explosion if these substances come into contact with a naked flame or spark. A moderate degree of knowledge, care and skill is involved and can be easily learnt, with an emphasis on understanding the need for proper ventilation and never to extract near an open flame. It is analogous to the education provided to patients and carers who require and use medical grade oxygen in their homes.

22. Extraction of other ''clean'' products which are safe and popularly used include the following:

a baking the plant materials in the oven to decarboxylate them and then extracting the medicinal properties from the plant properties using olive oil, or coconut oil;[337]

b. extracting the plant properties using alcohol or glycerine to extract resin from the plant, which is strained away from the plant material and the solvent is then removed by evaporating it off using heat (except C02 which naturally dissipates without heat). The heat also activates the THC in the plant. To ensure safety, a double boiler method is used, bringing water to the boil and then turning off the heat to remove the danger of naked flames or sparks. This is ideally conducted outdoors using an electric ''griddle'' stove or indoors with good ventilation. The substance in the double boiler becomes a thick oil;

c. alternatively, after extracting the plants properties into a solvent the liquid is strained and placed in a rice cooker, also preferably outdoors with good ventilation with a fan for good ventilation and to blow away fumes;[338]

As there is no open flame, the rice cooker enables a safe method of evaporating

solvents to produce a purged oil. The temperatures attained are sufficient that THC and other cannabinoid acids become activated. Rice cookers are popular for the heat control, so that THC can be activated (without being too high which would result in the loss of THC through evaporation.

This polar whole plant extraction is referred to as the "Rick Simpson"" method, which has been very popular amongst medicinal cannabis users.[339] If these methods are followed, the alcohol evaporates and usually leaves no residue, if done correctly.[340]

23. Non-polar solvents like butane may also be purged using a small amount of ethanol, which they cannot mix with, so are purged and the ethanol then evaporates cleanly. It is important to note that pure n-Butane is becoming more commonly available, however many inferior brands are either not completely filtered of impurities or contain a mixture of n-Butane, isobutane and or propane, sometimes mixed with an odorous substance (to help detect leaks) No matter how well these are purged post extraction, these substances can potentially be concentrated in extracts and cause negative effects when consumed, so it is important that high quality (5x filtered) or if possible, medical grade pure n-Butane is used.

24. One ounce (28.35 grams) of flower produces approximately 3 to 4 grams of full plant extract oil[341], however this varies according to the strain of the plant used. It is placed in sterile plastic measured syringes to keep the properties sterile and to allow for easy dose administration.

25. Potency of the quantity of THC:CBD is identified via laboratory reports in overseas jurisdictions. Within the CCV potency is determined on the basis of a compassionate growers horticultural taxonomical breeding history of their crop, odour (terpenes) and the results previously experienced from use.

26. Dosage quantity and formulation is dependent upon a person's condition. For example, some conditions including, MS, Lupus, Alzheimer's, Parkinson's, Autism, Migraines, Epilepsy and nausea, have been effectively controlled on one twentieth of a gram, which at this dose, has little to no psychotropic effects.[342]

27. Some cancers and end stage conditions are treated with much higher doses. However, dosage is always titrated. Tolerance levels are determined, with patients having previously used cannabis having greater tolerance than those who have not. Inexperienced patients are started on very low doses. As these patients tolerance increases, their dosage amount and frequency are similarly titrated up to take as much cannabinoids as they can comfortably manage without experiencing unwanted psychotropic effects.

28. Although there are a number of considerations when determining dosage and frequency of use it is believed that individual compassionate providers of medicinal cannabis within the CCV, in line with overseas current practices, have successfully employed dosing protocols for the use of concentrates and extracts. [The Commission is referred to: "Dosing of Cannabis and Cannabis Products" and "Correct Dosing" in this submission.]

29. The dosage for oils (with some variations depending on the ailment to be addressed and always adjusted for patient tolerance levels) is a titrated protocol. Doses between 1-5 mg are usually well tolerated without psychotropic symptoms[343]. Whatever the dose, oils can be syringed into gel caps (i.e. size "OO" gel caps hold 1 gram of oil) for easy administration.

30. The protocol[344] involves the following:

    - objective: for serious health conditions, to have a patient build up to taking one

third of a gram of oil every 8 hours over a 24 hour period consuming up to 60gm to 180 grams over a 6 to 9 month period for more serious health problems;

- starting dose for beginners:
- a miniscule dose of half the size of a grain of short grain rice (one eighth of an inch) or (0.01gm or 10 mg) every eight hours over a 24 hour period (3 times a day);
- On the 4th day a dose equal to the size of a short grain of rice (one quarter of an inch) or (0.02gm or 20 mg) every eight hours over a 24 hour period (3 times a day);
- 4 days later, the patient doubles the dose: equal to the size of 2 short grains of rice (half an inch) or (0.04 or 40mg) every eight hours over a 24 hour period (3 times a day);
- The patient continues to increase this dose by doubling it every 4th day until a person can ingest the equivalent of 16 grains of rice per dose or 8-9 drops of oil per dose, from a small plastic syringe/gel cap, which is roughly one third of a 1 gram of oil, which is given every 8 hours. 1 gram is just under 1 ml;
- This approach is recommended for balanced dose titration and to allow a patient's body to successfully build tolerance so that higher therapeutic doses can then be administered;
- When a person reports they do not feel any effect or only a slight effect – this is an Indication of correct dosage for those who have not previously taken cannabis before;
- Most patients successfully build up to one third of a gram three times a day within a three week period. Some patients may take a little longer. A person should only increase the amount and frequency of the dose at the rate they can comfortably tolerate. The idea is to slowly increase to an individual's own tolerance level;
- When produced from Indica strains, oils has a sedative effect, which dissipates generally after 1 hour;
- To be taken orally and applied to the gums, or on a piece of bread or fruit;
- Maintenance dose: 1 drop a day (1/20th of a gram or 100 mg)[345] or 1 gram a month

31. To further increase bioavailability of the cannabinoids and to make measuring the oil easier, the concentrated cannabis oil can also be diluted and added to a carrier oil, such as coconut oil or olive oil.

32. The choice of carrier oil will also depend on patient's tolerability and preferences. For example olive oil is a long chain fatty acid, whereas coconut oil is a medium chain fatty acid. Both are absorbed at different rates and in different manners by the body. Coconut oil is absorbed much more quickly and goes straight to the liver. Olive oil on the other hand, being absorbed by the lymphatic system takes a lot longer to reach the liver. The liver plays an important role in the psychotropic effects experienced through THC, converting delta9-THC into the more psychotropic form of 11 OH-THC. Coconut oil can be beneficial for faster pain relief and or to induce sound sleep. If these effects are not immediately desired, then olive oil is used instead to provide a slower acting and therefore less intense, but longer lasting sustained effect.

33. The following represents a treatment protocol used in a Medicinal Cannabis Clinic in Portland, USA:

- a standard ratio of 20 parts coconut oil to 1 gram of cannabis oil can be used[346] but the ratio can be adjusted (higher or lower) according to tolerance level and as tolerance level builds;[347]
- taking 20 ml/gram of coconut oil and melting it over a low heat, 1 gram of cannabis oil is then added and the mix is then syringed into measured gel caps for easy administration; [348]
- for example, size''00'' gel caps hold 1 gram of the mixed oils. At a 20:1 ratio a quantity of 21 x1 gram ''00'' gel caps is produced.[349] At this ratio, one capsule is taken each 90 minute interval to observe effects. If the patient does not feel any effects the patient takes another capsule and waits a further 90 minutes;[350]
- this process is repeated until the patient starts to feel some effects at which point the patient stops dosing. The number of capsules is noted, which determines the correct maximum dose for that patient at that time; [351]
- when the patient can digest more than 2 capsules per day, the concentration ratio is made more potent: 10:1 ratio. At this level, one capsule is taken daily and is increased up to 2 capsules daily;[352]
- at a ratio of 5:1 the dose is the same, one capsule daily working up to 2 a day.[353]
- at a ratio of 1:1 one capsule is taken daily working up to 2 capsules daily, with one dose in the morning and one in the evening 2 hours before bed;[354]
- finally, the patient takes 1 gram of straight cannabis oil undiluted (in 1 gram ''OO'' sized gel caps) and takes between 1 to 3 or more grams of cannabis oil daily, depending on the condition being treated;[355]
- the capsules can be swallowed or their content can be added to hot drinks and taken as a tea.

34. Concentrates such as oils, can also be applied topically to the skin (i.e.: for skin cancers) or mixed in with carrier oils and applied for less aggressive skin conditions.

35. It may be made into a salve, where cannabis is melted into coconut oil and combined with lecithin or bees wax and when cooled rubbed into the skin or as a cream, where the cannabis is heated in shea butter and/or carrier, then allowed to cool before being applied.

36. Cannabinoid oils and oil mixtures are also applied to the skin to address pain and inflammatory conditions. Anecdotal evidence suggests that cannabis salves and creams are effective for treating[356]:

- Superficial wounds, cuts, corns, acne, furuncles, nail fungus;
- Lips, herpes, fever blisters
- Dermatitis
- Psoriasis
- Rheumatism and arthritis pains
- Phlebitis, venous ulcerations
- Haemorrhoids
- Back pains, cramps, muscular pains sprains
- Menstruation pains
- Throat problems, asthma/respiratory difficulties, bronchitis

- Migraine, head pain, tension headaches.

37. Cannabis oil added to coconut and lecithin oil (to assist the cannabinoids crossing the cell membrane) is commonly used in a ratio of 1gm of cannabis oil to 16 ounces of carrier oil.

38. Due to the knowledge and sill involved in their extraction, non-polar extracts, Co2 or butane, are not readily available in Australia. Polar ‘’whole plant’’ extracts are becoming more readily available in Australian and are producing dramatic therapeutic benefits and results. They are increasingly sought out by many patients across the globe for this reason. Rick Simpson reports[357] the following conditions amongst those that have been cured and or received benefits from cannabis oils:

    - Cancers
    - Multiple Sclerosis
    - Lupus
    - Diabetes
    - Cardiovascular health & blood pressure
    - Asthma skin conditions & burns
    - Glaucoma and ocular health
    - Thyroid disorders
    - Chronic pain
    - Migraine
    - Scars, ulcers, warts, moles
    - Back pain, scoliosis
    - Menopause & PMS
    - Weight management
    - Sleep Disorders, Insomnia
    - Anxiety, depression, paranoia
    - Heavy Metal Toxicity.

39. The is submitted that:

    - concentrates and extracts are versatile in their form of application and cater for a wide range of patients and conditions. Extracts are particularly versatile and medically useful, as they can be added to baked goods in measured doses. Non-polar extracts can also be used in a vaporizer, to provide quick pain relief or to address acute onset symptoms such as seizures;
    - concentrates that are vaporized, are an expedient and can be a cost effective method to provide relief from acute onset debilitating symptoms;
    - it is a discreet, clean and easy to use method;
    - it is accessible: it can be safe and easy to make and use when correct precautions are taken;
    - dosage is easy to work out, titrate and administer for patients. Effects can be

easily managed and controlled by patients in contrast to oral pharmacological alternatives with standardizes doses that have delayed onset effects up to several hours;

- dosage is easy to work out and administer for patients and the effects thereof, can be easily managed and controlled by patients;
- increased medical potency means less product is required for use;
- administration of therapeutic properties: activated or inactivated, can be chosen to suit the patient's needs and circumstances;
- it is a desirable option for non smokers, persons with smoke and or strong odour sensitivity that is associated when burning dry plant matter;
- may be preferred by those who cannot consume edibles due to dietary or associated health issues commonly associated with food for example allergies and or sensitivities;
- it is a popular choice for all these reasons; and
- regulation would address manufacturing issues, quality of product, constituency of the cannabis: THC:CBD content, mould, bacteria, residual chemicals together with potency/serving size/dose quantities, labelling, tamper proof packaging, styling (to differentiate from other products), with appropriate warning.

Concentrates and extracts are a clean, efficient, effective, versatile, practical and accessible method of THC delivery to the human endocannabinoid system. They address multiple patient needs and are extremely popular for this reason. They are a vital form of cannabis medicine that needs to be included as an option for use, in any proposed medicinal cannabis scheme. To exclude the use of any form of concentrate, extract or their administration methods s an option, will deny some patients access to a therapeutic to alleviate suffering and or improve their quality of life.

EDIBLE CANNABIS PRODUCTS

1. Cannabis infused foods (i.e. hash brownies and space cakes) informally referred to as cannabis edibles, are food products made with cannabis in herbal or resin form as an ingredient.
2. They are an alternative means of obtaining cannabinoids without smoking or vaporizing. Cannabis is fore mostly, a herbal food and is easily and readily incorporated into to butter or coconut oil (for baking/cooking), milk, honey and directly into meals, sweets, baked goods/snacks and drinks. The bioavailability of cannabinoids is affected by the presence of, type and quality of carrier oil, as previously discussed.
3. Cannabis Oil is a general term used to refer to extracts but it can also refer to cooking oil infused with cannabinoids, which can create some confusion. Best results are achieved when the originating material is completely decarboxylated prior to the extraction of the plants properties into oil. Extraction methods include simmering fat/oil/butter and cannabis in a double boiler, pot, frying pan, or slow cooker then straining the oil from any plant material. The medicinal properties of the plant, having been transferred to the oil, can then be incorporated into recipes that call for standard fats. However, the temperature is monitored so it does not exceed the evaporating point of the cannabinoids.
4. There are a wide variety of such products available to patients in overseas jurisdictions.

Products are tested in laboratories and labelled to identify potency and regulations govern the mgs of THC per dose, which in Colorado, by way of example, is 10mg of THC per serving portion.

5. It is thought that oral consumption of cannabis infused foods, either alone or in combination with inhalation, is a more efficient and long lasting way to absorb cannabinoids than via inhalation alone.[358] This may be due to the presence of fats and oils that aid the bioavailability of cannabinoids in the body, due to biochemical reactions in the stomach which convert THC to stronger variations which are not obtained through the lungs, and due to the long acting operation provided by the underlying level of cannabinoids over several hours, that would otherwise be gone after 30 minutes of inhalation of the same dose.

6. THC however, is 3 to 5 times more potent when smoked or inhaled, than when it is ingested. A cannabis cigarette containing 2 per cent THC is said to deliver less than 10 milligrams of THC to the lungs, with 30 to 50 milligrams of THC ingested orally being required in order to provide the same therapeutic benefit.[359] Due to gut absorption, it has been noted[360] that patients needing edible cannabis products, will require 3 to 5 times the quantity of cannabis than they would require if it was smoked or inhaled

7. Edible products may be activated (THC) or inactivated, depending upon whether the cannabis has been decarboxylated. Some research suggests that heating cannabis to 122 °C for approximately 27 minutes is needed to convert the THC:THC acid to THC-delta-9, however other methods use lower temperatures for longer periods or vice versa.[361]

8. The effects of THC are not as immediate and experienced gradually when ingested as opposed to when smoked or vaporized, due to slower absorption of the THC from the digestive tract, than the lungs. It may take up to two hours for edibles to reach their full effect, which may last from 2 to 8 hours[362]. The liver processes oral doses before entering the bloodstream and it is in the liver where delta 9 THC is converted into its more potent counter part 11-OH-THC, which crosses the blood brain barrier more easily.[363] The effects however may be more immediate where cannabis is incorporated into coconut oil, a medium chain fatty acid that is absorbed through the intestines into the portal vein than through the liver.

9. In medicinal cannabis schemes operating in the USA, regulations specify the percentage of THC, CBD, terpenes and other properties in the goods, as well as dosage per size or serve. The dosage is set out in milligrams of THC per standard dose, so the effects are quite predictable (with allowances being made for quicker onset of effect with products high in fat as distinct from sugar, as fat increases the bioavailability of THC up to 50%). This makes identifying servings/quantities required to achieve dosage relatively easy.

10. In Colorado, USA where cannabis is available for medicinal and recreational purposes, products may contain up to 100 mg, but they must be made in such a way that they can be broken down into pieces of 10mg each. [364]10 mg is the standard dose, for both recreational and medicinal cannabis edible products with manufacturers currently moving towards separately wrapped child and tamper proof, blister packaging, as well as smart graphics[365] Indicating activated content per serving of product consumed. Warnings to keep out of the reach of children are stated. Regulations regarding the provision of instructions regarding dose and distinguishing packaging from other familiar edibles on the market, are currently being proposed.[366]

11. Sampling different edibles and finding the right dosage can take some time to find the correct products and dosage/size/regime. As with other cannabis medicines, titrating

the serve/dose upwards in terms of quantity (to ensure that each dose effectively relieves symptoms) and frequency (to maintain constant relief of symptoms) is the recommended approach. The basic principle is to try a very small sample of the edible product and wait an hour to test the effect, gradually increasing the size of the dose used to test the boundaries of what dose works best and at what intervals. If a little piece of a product has a strong effect when eaten then it is extremely potent and should be dosed accordingly and so forth for less potent products.

12. The recommended starting test dose for such products is half the standard dose (i.e. 5 mg), which accounts for variability in patients sensitivity to THC and the aforementioned variable bioavailability of THC depending on the lipid content of the food it is contained in.

13. The approach of gradually increasing the size of doses (i.e. 5 mg) and the regularity they are taken is also used by patients suffering from conditions such as late-stage cancers, though their dosages will be much higher than that needed for symptomatic relief of their nausea and pain associated with chemotherapy, as the treatment regimes required to kill cancers involve complete saturation of their systems with as much THC as they can handle without having unpleasant psychoactive effects.

14. It is submitted that:

- edibles are more effective at delivering a long acting cannabinoid medicine regime to treat chronic symptoms than inhaled cannabis medicines;
- dose is easy for patients to work out and administer;
- administration of therapeutic properties –activated or un-activated edibles, can be chosen to suit the patient's needs and circumstances;
- variety of forms make taking cannabis medicine more palatable, which is particularly important for children who may not otherwise enjoy the taste;
- it is a convenient and more discrete form of dosing/medicating than other methods;
- it is accessible and can be safe and easy to create and use;
- as the market develops, organic, gluten free, dairy free, sugar free, GMO free, vegetarian and/or vegan products would become available, making this a very accessible form of medicine for a number of people with different dietary needs;
- potency requires less product –making it a productive, potentially more cost effective substance than smoking or vaporizing dry plant material;
- it is a desirable option for non smokers, persons with smoke and or strong odour sensitivity that is omitted when burning dry plant matter;
- quality and potency of cannabis and availability of concentrates can be addressed and identified through the adoption of an appropriate regulatory framework, that includes laboratory testing and labelling;
- it is suitable for patients who do not need or desire the immediacy of effects of THC that can be achieved via other methods;
- it is a popular choice for all these reason; and
- regulation would address manufacturing issues, quality of product, constituency of the product including: THC:CBD content, mould, bacteria, chemicals together with potency/serving size/dose quantities, labelling, tamper proof packaging, styling (to differentiate from other food products), with appropriate warnings.

Edibles are an effective, versatile, discrete and accessible method of THC delivery to the human endocannabinoid system. It addresses multiple patient needs and is extremely popular for this reason. It is an important form of cannabis medicine that needs to be included as an option for use, in any proposed medicinal cannabis scheme. To exclude this as an option, will deny some patients access to a therapeutic to alleviate suffering and or improve their quality of life.

VAPORIZING FLOWERS

1. Dried cannabis flowers can also be used in a device called a vaporizer to produce an activated aerosol medicinal.

2. The dry plant material is heated using electrically generated conduction or convection methods, causing the active properties to vaporize, without burning the plant material. The vapour is inhaled via a tube or collected in a balloon and then inhaled. The raw plant material can be used more than once with this method. Used material can be re-ground to expose more surface area so that greater medication can be extracted during subsequent use.

3. In addition to dry plant material, concentrates and extracts in small quantities, are often vaporised separately or in combination with flowers, and can give a more potent and long lasting effect).

   A small water pipe (an ''oil rig''), which resembles a glass bong, is commonly used for this purpose. The distinctive features are: nail or skillet made of ceramic, glass, quartz or titanium which serves as a heating plate, and a glass dome in which the vapor collects and concentrates prior to inhalation. Heat administered by a hand-held blowtorch is used to heat the plate. A tool called a ''dabber'' (i.e. glass rod or dental pick) is used to dab the oil onto the plate, which is then heated, vaporized and inhaled.

   Today there are many sophisticated electronic vaporizers, which can be used for this purpose that do not have the visual similarity to a bong or oil rig. These modern electronic devices utilize heat control mechanisms allow the vapor to collect into a balloon or for it may be inhaled directly after passing through a cooling system. These can range from desktop devices to a portable pen ("vaporizer pen'' similar to an asthmatic inhaler), which are the most convenient and discrete methods of cannabinoid titration dose delivery available today.

4. Like smoking, the effects of vaporizing are immediate compared to other forms and application of using cannabis. This allows a patient to determine the amount of medicine they need to consume and to titrate their dose accordingly. Further, a number of cannabinoids and plant properties, including terpenes, can be delivered via this method by controlling the heat. [367] For example, terpenes begin to vaporize at 126.0 °C (258.8 °F), whereas THC, CBD and CBN do not do so, until they reach their boiling temperatures of THC: 157 °C (315 °F) CBD: 160–180°C (320°F-356°F) and CBN: 185 °C (365 °F).[368] For example, at a low temperature the patient might get benefits from some terpene availability and when increasing the temperature to 157 °C (315 °F) they will obtain THC from without vaporising the CBD, which has a higher boiling temperature. ''Already vaped buds'' ("AVB") can then be re-used at a higher temperature to extract the CBD.

5. Vaporization produces significantly less carbon monoxide is formed than smoking[369] and vaporizers deliver almost pure cannabinoids, with almost no tar, making this a much safer delivery method than cannabis cigarettes or water pipes[370]. THC can be vaporized at temperatures as low as 140 degrees Celsius[371] with the majority having

been vaporized around 185 degrees Celsius[372]. Benzene and other carcinogenic vapours do not appear until 200 degrees Celsius,[373]

6. Rising doses of 2, 4, 6, and 8 mg resulting in a total dose of 20mg used in a clinical trial has shown that approximately 11 mg is inhaled from a balloon. 65% is found to reach the lungs or between 6-8 mg. Final uptake was assessed as comparable with smoking, but without the negative effects associated with combustion.[374]

7. Controlling the temperature on vaporizing devices is important as it affects the medicinal properties and the amount of activated THC absorbed per inhalation. Lower vaporization temperatures give a more psychoactive high as mostly THC and terpenes are delivered, with higher temperatures allowing for a more sedative effect as CBD starts to evaporate also. Temperature control on vaporizing units allows a therapeutic user to have greater dosage control, especially with regard to specific cannabinoids.

8. Dosing and therapeutic outcomes are also determined by quality of cannabis used, weight/quantity of plant material or use of different concentrates, together with whether a balloon, direct-draw through a glass or silicon ''whip'' or vaporiser pen is used. With a balloon, its size and how long it is used can effect the medicinal benefits, since when used with small amounts of cannabis, a large or leaking balloon will not allow sufficient concentrations of vapour to provide the desired medicinal effects. With a vaporiser pen, the type/how much concentrate is used are all relevant. Regulated products and services within a medicinal cannabis schemes can overcome these concerns[375].

9. Vaporizing has been found to be an effective route of administration of THC [376]with 54% of the dose of THC reaching the balloon.[377] A study of the ""Volcano'' vaporizer in 2006, determined: ''the Volcano a safe and effective cannabinoid delivery system…The pulmonal uptake of THC is comparable to the smoking of cannabis, while avoiding the respiratory disadvantages of smoking."[378]

10. For experienced users the approximate potency can usually be determined by inhaling the smoke or vapour from a small dose of the product, and waiting 5 to 20 minutes to determine the effects.

11. A usual starting dose for those who have used cannabis before, will be around 0.25 of a gram of standard flowers, or its equivalent in concentrate or extract form at 0.05 gram (or 50 mg) (as extracts are around 5 times more potent than the flowers). The effect of a 0.25 gram dose of a dried flowers that is 17% THC such as the very popular Jack Herer strain can therefore be achieved through a tiny bit of Co2 or BHO oil extracted from the same plant material which is 97% THC.

12. Experienced users can then determine based on effect, what their optimal and ongoing dose should be.

13. For inexperienced users the test dosage is half that for experienced users, so around 0.125 of flowers should be trailed gradually working up to 0.25 or beyond as thee patient's experience and tolerance builds.

14. Vaporizing is favoured by overseas Medicinal Cannabis Practitioners and is currently employed in hospitals in Israel where patients who are prescribed cannabis have vaporizers in their hospital rooms.

15. Vaporizing is a popular choice with medicinal cannabis users both here and overseas, not only because the user has more control over dose and the effects thereof, but it is also a discrete means of consuming cannabis. The odour associated with burning cannabis is avoided and portable pen like apparatus, allows for discreet use in front of others, without disturbing or affecting them in much the same way an e-cigarette dose in contrast to smoking tobacco.

16. It is submitted that:

- vaporizing is a clean, expedient and cost effective method to provide relief from many debilitating symptoms and improves quality of life;
- vaporizing is effective for fast relief of acute symptoms;
- accurate dose regimes are easy to determine and administer;
- dosage can be easily titrated up or down for desired therapeutic effects;
- dose is easy to titrate and effects can therefore be easily managed and controlled by patients, contrasted to oral pharmacological alternatives with standardized doses with delayed onset effects from 1-6 hours;
- greater bioavailability of cannabinoids than oral pharmaceutical alternatives;
- adjustment in heat settings on vaporizers allow lower heat applications to deliver the therapeutic terpenes in the plant along with THC;
- patients have control over dosing and the therapeutic effects of the cannabinoids;
- new high tech oil vaporizing pens and asthmatic like inhalers, make the application of the medicine, clean, easy, convenient and a much more discrete form of accurately dosing and medicating, than other methods;
- Vaporizing requires less product and what is used can be re-used several times making it a more medically effective and potentially more cost effective method of administration than smoking;[379]
- it is a desirable option for non smokers, persons with smoke and or strong odour sensitivity that is endured when burning dry plant matter during smoking;
- quality and potency of cannabis and the availability of concentrates can be addressed and identified through the adoption of an appropriate regulatory framework that includes laboratory testing and appropriate labelling, in terms of potency and purity; and
- regulation would address manufacturing issues, quality of product, constituency of the product: THC: CBD, mould, bacteria, chemicals together with potency/serving size/dose quantities, labelling, tamper proof packaging, styling (to differentiate from standard food products), with appropriate warning.

Vaporizing is a clean, safe, fast, efficient, effective, convenient and discreet application method for the delivery of cannabis medicines. It addresses multiple patient needs, and is becoming extremely popular for this reason. It is a vitally important form of cannabis medicine for patients with acute symptoms and must be included in any medicinal cannabis scheme. To exclude this as an option, will deny some patients access to a fast acting therapeutic to alleviate suffering and or improve their quality of life.

CONTROLLING UNDESIRED SIDE EFFECTS OF CANNABIS MEDICINE

1. In addition to dose titrating, other successful methods commonly employed by CCV and Medicinal Cannabis Clinics in other jurisdictions of mitigating the effects of THC include the following:

    - using strains and products high in particular terpenes (i.e. Myrcene)
    - using strains and products in particular cannabinoids (i.e. CBD)
    - taking 250-500 mg of Citicoline one hour before taking cannabis medicine.[380]

2. Citicoline is a supplement currently recommended for use in, head trauma, cerebrovascular disease, stroke, and neurodegenerative disease including age-related memory loss, dementia and Parkinson's disease, as well as in ADHD and glaucoma.[381]It has several medicinal effects including improved focus for sufferers of conditions in which sufferers are unable to concentrate, however its primary purpose in cannabinoid therapy is to inhibit the psychoactive effects of THC.

3 The U.S. National Institute on Drug Abuse (NIDA) has recognized the value of Citicoline, a supplement, in reducing the psychoactive effects of THC. In November 2013, they issued a participation request (ID: NCT00158249) asking for volunteers and defined 'heavy' cannabis users to take part in a clinical trial.[382]

4. Citicoline is regarded as safe and has a low toxicity profile in both animals and humans. [383]Clinical doses of 2000 mg per day have been observed and approved, with minor adverse effects, such as stomach pain and/or diarrhoea experienced.[384]

DOSING OF MEDICINAL CANNABIS

1. It is acknowledged that the medical profession in Victoria may have some reservations on how to prescribe a herbal substance that is not currently a registered medicine with dosage formulations and or guidelines that are appraised and prescribed in the context of clinical trials.

2. This is understandable as such is customarily the domain of herbal and naturopathic practitioners who are quite adept at prescribing doses of herbal substances as therapeutic agents, producing general extractions and converting dose in milligrams of active ingredients and/ or back into grams of raw dried/cured plant materials using standard TGA approved drug ratios[385]. Accordingly, such practitioners are ideally suited to prescribing cannabis and working with and/or alongside medical practitioners in a medicinal cannabis scheme.

3. Compassionate providers of medicinal cannabis within the CCV have employed dosage guidelines and have imparted knowledge regarding their administration and use successfully for many years. This approach is also consistent with that taken by their counterparts in overseas jurisdictions operating in lawful medicinal cannabis medical clinics.

4. In line with current practices of herbalist and naturopaths, as well as General Medical Practitioners treating patients using medicinal cannabis in overseas jurisdictions, the CCV approaches appropriate application and dosage through a consideration of factors, which include but are not limited to[386]:

    - patient medical history;

- identification of ailment & /or symptom relief needs;
- the need for relief from acute and/or chronic symptom;
- desired activity level and functional requirements of the patient;
- strain variety and availability;
- potency in terms of THC and presence of other cannabinoids and certain terpenes;
- form (i.e. oils, tinctures and edibles = fat content=higher bio availability and therapeutic effect);
- prior use and tolerance;
- different routes of administration;
- weight of raw and dried plant materials or extracts expressed in grams and/or mgs of THC, CBD etc., per gram; and
- titrating doses accordingly to achieve identified therapeutic treatment objectives.

In short, the approach is a highly individualised one, utilising dosing titration. As Carter, et al in "Medicinal cannabis: Rational guidelines for dosing'' state:

> "Cannabis has many variables that do not fit well with the typical medical model for drug prescribing. If the plant is used, the variations are extreme. Plants vary immensely by phenotypes, and even the time of harvest affects which cannabinoids are present and in what percentages. An individual may be much more sensitive than another, heavy smokers may experience different chemical effects than light smokers and ingestion may alter bioavailability. … (cannabinoid) combinations are important to medicinal users of cannabis as a number of positive synergistic effects could be involved. All of these points make it imperative that the dosing is highly individualized, so a patient- determined, self-titrated dosing model is recommended. This self-titration model is acceptable given the variables discussed above, as well as the low toxicity of cannabis."[387]

THE CORRECT DOSE OF MEDICINAL CANNABIS

1. A consideration of the matters referred to at paragraph 4 represent standards to ensure that accurate dosage is attained and that a patient obtains symptom relief. As Aggarwal et. al in "Dosing Medical Marijuana: Rational Guidelines on Trial in Washington State." emphasize, standards are necessary in order to:

   ''maximize the potential for symptomatic relief. To do anything less would be unethical"[388]

   Symptomatic relief for the patient must be a prime consideration when approaching a dosage regime.

2. The potency of the medicinal cannabis/products used is also an important and relevant consideration in establishing dosage regimes, as a cannabis product which has 20% THC will be twice as potent as a product that has only 10% THC.

3. Potency will vary according to strain of cannabis used, the amount or ration of THC:CBD and the form and proposed application to be employed. However, much higher doses of THC are tolerated when given as a whole plant therapeutic cocktail.[389]

4. A further consideration relevant to dosage and patient requirements is whether the strain being considered for therapeutic purposes contains CBD and if so, its ratio of

THC to CBD, as CBD blocks both the psychoactive and medicinal effects of THC.

5. Most medicinal cannabis contains high THC and is in fact the preferred choice sought by most patients for its therapeutic operation and effects[390] Some of the original landrace strains and modern strains contain levels of CBD resulting in products that range from High-THC with small amounts of CBD, through to products with a 1:1 ratio of THC:CBD and or products with low-THC/high CBD.

6. As CBD counteracts or buffers the effects of THC, the THC is less potent and therefore less effective. In Canada, scientists and Medicinal Cannabis Practitioners recognise this and use the buffering effect of CBD in order to administer higher doses of THC, than might otherwise be tolerated at such levels, by these patients. This has been found to be particularly useful in the management of chronic pain conditions.[391] The exact mathematics of how much CBD inhibits how much THC is understood to be the proprietary knowledge of a few companies. All the same, the degree to which CBD inhibits THC in this manner can be determined via titration and patient response. For example, trialling a product that is high in CBD (either alone or in combination with THC) will not relieve most symptoms that are easily controlled by a high-THC/low CBD product alone.

7. Similarly, the route of administration and form of product will also play a determinant role in working out dosage.

8. The Health Canada Guidelines for Physicians states that "In a published federal document, submitted on record to Canadian Congress, Dr. Jones opined that: “THC has been estimated to be 3 to 5 times more potent when inhaled than when ingested.” He then gave a concrete example in that: “A marijuana cigarette containing 2 per cent THC would deliver slightly less than 10 milligrams of THC to the lungs where most is probably absorbed. But to reach an equivalent state of intoxication when taken orally, from 30 to 50 milligrams of THC would have to be consumed.” As previously stated, this means that the dose of cannabis required to reach efficacy when administered through digestion needs to be between 3-5 times the amount of cannabis/cannabinoids required to achieve the same effect from medicines administered through inhalation. This also has implications for supply, as patients who are prescribed i.e. 5 grams per day by inhalation will need to be prescribed 15-25 grams per day by ingestion.

9. Consequently, 30 grams (30,000 milligrams) of cannabis prescribed over a 2 week period for administration by inhalation at just slightly over 2 gram (2,000mg), needing to be 3x stronger to obtain the same therapeutic effect from edibles would only last a patient (3 x 2,000 mg=6,000mg daily) so would only last 5 days if consumed via digestion instead.

10. Patients tolerance to cannabis must also be addressed in determining the accurate dosage required for an individual patient. Whilst body weight is not relevant to tolerance level and dosing, genealogy has found to play a distinct role[392]. Individuals of Celtic decent (Irish, Scottish and Welsh heritage) are found to require three to five times more cannabis than those of European, Asian or African descent.[393] Canadian scientists have observed that those of Celtic origins will frequently start with 50 to 100 mg of THC without experiencing any reported adverse effects, in contrast to those of European origin who start at 20 to 40 mg of THC[394].

    Those who have used cannabis previously will have a higher metabolism tolerance threshold level for cannabis, than those who have not. Such patients will require significantly larger doses of cannabis to achieve a therapeutic effect.[395] This is in line with current medical practice standards (i.e. with opioids) and is acceptable given there is ‘’essentially no risk for overdose.[396]’’

Patients who require higher levels of THC may then require additional cannabis to obtain the effective therapeutic outcomes associated with a product that contains less or no THC. This is a relevant and further consideration applicable to ascertaining the right quantity and dose of cannabis medicines, and has implications for supply, since patients using products that contain CBD, may need higher legal quotas in terms of the amount of medicines they are allowed to posses or grow.

For patients who have not used cannabis before or who have low tolerance levels, they are started on a very low dose, as previously stated.

The approach is: ''start low and go slow.'' Slowly increasing or titrating, the size and frequency of dosage irrespective of form and method of administration, to tolerance and symptom relief level. This is the general approach to dosing used both here and overseas[397]

11. As previously acknowledged, there are contrary reports on the potency of THC in cannabis products in the scientific literature.

12. Due to the current laws of prohibition, which preclude possession, and use of the plant, the plant materials cannot currently be subjected to laboratory analysis for identification and or confirmation in Australia. Potency of the cannabis flowers are currently determined by: smell (to assist in identification of types and concentration of aromatic terpenes as they have a distinct odour with higher odour generally corresponding to higher cannabinoid levels), taste, visual appearance (to identify presence, colour and quantity of trichomes- often by using a microscope) and tactile sensation (to determine the presence of the sticky resin secreted by the trichomes). Laboratory analysis under a proposed medicinal cannabis scheme would however, help establish potency in a way that would aid confidence and increase therapeutic outcomes associated with dosage regimes.

13. Whether the exact content of cannabinoids (i.e. THC: CBD) in a product are known in milligrams, (as determined through laboratory analysis or not), the dosing schedule is nonetheless still based on titration, where a patient starts with a small measured dose of THC contained in flowers concentrates, extract, tinctures and or/edibles at regular intervals several hours apart, and gradually increases the amount taken and the regularity of the dose in order to find what gives them best relief of symptoms, without experiencing unwanted psychotropic effects.

14. As cannabis has low toxicity and no overdose potential, correct dosage (which incorporates potency and the considerations referred to a paragraph 4 above) can be easily be established and managed via titration in terms of frequency and quantity. As an additional measure, some Medicinal Cannabis Practitioner in overseas jurisdictions prescribe CBD capsules with higher doses of THC, in order to buffer and lessen any possible unwanted side effects.

15. This approach is currently employed by Medicinal Cannabis Practitioners in overseas jurisdictions[398]. It is also widely employed in aromatherapy, herbal, homeopathic, naturopathic and general mainstream medicine. Although clinical trial results may assist doctors in identifying specific dosage regimes for particular symptoms and/or conditions, they are nonetheless a mere guide, as every patient will have different medical needs that are addressed by fine tuning medical treatment. Dose titration is commonly applied in mainstream medical practice today, as noted by Carter, et al in "Medicinal cannabis: Rational guidelines for dosing'' state:

'this construct is not unique to cannabis. There are other drugs that have relatively low toxicity and high dosing limits (gabapentin being one notable example), and are titrated to effect.""

16. Based on patient average daily doses of cannabis plant material and products in other jurisdictions, and using the FDA approved dosing paradigms for dronabinol (THC), Carter et. al in "Medicinal cannabis: Rational guidelines for dosing,'' [399]set forth one approach in which a medical practitioners could successfully calculate, titrate and adjust, individual patient daily doses of cannabis plant material and products as required by their patients. Determining an accurate and correct dose of cannabis plant material and or products is a simple matter of dose titration and mathematics.

17. Many patients are prescribed a combination of inhaled and ingested cannabinoid products. Inhaled medicines may be required to assist the patient with acute onset symptoms when they arise, while a regime of edible doses is generally used to control chronic symptoms and prevent acute symptoms from occurring. With flexibility to increase the oral regime as tolerance increase, frequency and dosage of inhaled doses can be reduced.

    This approach is also employed at times of respiratory difficulties such as sore throats, cold or flu, during which times, inhalation can be difficult. Using various strains, forms and administration methods serves to assist in achieving optimal cerebral functionality based on patients symptom and general medical needs, balanced against a heavy body, sleepy and relaxed effect. Products high in a particular cannabinoid and or terpene can be combined in various ratios for combination therapeutic purposes, but can also be taken hours apart in order for the full effect of each to be experience and to achiever optimal therapeutic outcomes. In many cases the best results can only be achieved by separating the administration of the prescribed doses of THC and CBD by up to several hours.[400]

18. It is recommended therefore, that medical/Medicinal Cannabis Practitioners who are educated about the endocannabinoid system and who are given prescribing rights under a medicinal cannabis scheme should ideally be required to stipulate:

    - the patient's Maximum Total Daily Dose ("MTDD") and/ or Total Daily Dose (with patients starting lower and titrating up to a MTDD) in grams, ounces mcg's and or mgs;
    - each specific cannabinoid as a ratio to other cannabinoids;
    - terpene requirements or restrictions (i.e. No Myrcene to avoid drowsiness);
    - product and form (i.e. flowers, concentrates, extracts, tinctures, edibles);
    - methods of administration;
    - direction as to when to take the specific cannabinoid (i.e. 3mg of Indica flowers 1 hour before bed; 3mg of Sativa flowers 3 x per day or 8 hr intervals);
    - directions for use and dosage schedule for each cannabinoid which is required to be taken separately (i.e. the period of time between doses for the different cannabinoids, using grams, ounces, mcg's and or mgs);
    - where more than one form of cannabis is recommended (i.e. "combination therapy') whether prior cannabis medicines are to be maintained, reduced or discontinued;
    - where more than one form of cannabis is to be taken- separate prescription for each form of cannabis should be issued.

    Total medicine quantity in a prescription would equate to either the patient's Maximum Total Daily Dose of medication stipulated in a patients treatment plan or where titrating

the dose up to that level, a Total Daily Dose over the duration of the prescription period, having reference to all forms used in combination therapy and all prescriptions issued.

19. Separate prescriptions for different forms of cannabis ensure:

- accurate dosage for patient's;
- the avoidance of errors by a doctor or the Medicinal Cannabis Practitioner in dosing which might leave the patient without sufficient medicine;
- makes dispensing and tracking of cannabis provided to the patient's easier and reflects current pharmacy practices in the dispensing of medications; and
- collection of specific or aggregate patient data, including dosage regimes for specific symptoms or conditions would also be useful in any evaluations for regulatory and or scientific research purposes.

PART FOUR

REGULATORY FRAMEWORK OF A MEDICINAL CANNABIS SCHEME

REGULATORY FRAMEWORK OF A MEDICINAL CANNABIS SCHEME

1. It is acknowledged and/or submitted that:

1.1 proposals for the operation of a medicinal cannabis scheme in Victoria must work within an existing frame work of state, federal and international laws;

1.2 the Commonwealth is responsible for regulating the quality, safety and efficacy of registered medicines, as well as scheduling poisons and controlled substances under the Therapeutic Goods Act 1989 (Cth) and the Commonwealth Standards for the Uniform Scheduling of Medicines and Poisons ("SUSMP" or "The Poisons Standard");

1.3 the Victorian State Government is responsible for regulating the sale, supply, possession, handling and use of registered medicines and scheduled poisons and controlled substances under the Drugs Poisons and Controlled Substance Act 1981 (Vic) and the Therapeutic Goods Act 2010 (Vic) ("TGA Vic"). The Commonwealth SUSMP has been incorporated into the Drugs Poisons and Controlled Substances Act 1981 (Vic). S. 5 of the Therapeutic Goods Act 1989 (Cth) and S 6. (2) Therapeutic Goods Act 2010 (Vic) provides for the application of the Commonwealth legislative scheme to Victoria. Victoria however, has the power to adjust the extent to which the Commonwealth legislation applies to Victoria;

1.4 a drug can be a poison and simultaneously, a controlled substance under lawful prescription and supply under Drugs Poisons and Controlled Substance Act 1981 (Vic) and regulations;

1.5 cannabis is regulated in Victoria as:

- both a poison and controlled substance;
- a registered medicine under schedule 8 SUSMP and;
- a drug of dependence and misuse;

1.6 cannabis is a substance prohibited by law. Federal and State criminal sanctions operate in relation to the:

- administration and use;
- possession;
- cultivation;
- manufacture;
- trafficking or
- supply and sale;

of cannabis, unless otherwise authorised by law;

1.7 part 5 of the Drugs Poisons and Controlled Substance Act 1981 (Vic) provides that such activities are not unlawful when authorised under the act or by regulation;

1.8 the Criminal Code Act 1995 (Cth) provides a defence to the unlawful acts associated with cannabis referred to, where they are authorised or excused by a law of a state or territory;

1.9 cannabis used for medical or scientific research, teaching or training purposes may be lawfully permitted with the approval of the federal and or Victorian State Government Ministers of Health. Such permission has not been granted to date;

1.10 the Therapeutic Goods Act 2010 (Vic) could be amended to authorise activities associated with the use of cannabis for medical purposes. In doing so, Victorians would have a defence to any acts associated with the use of cannabis, under the Criminal Code Act 1995 (Cth);

1.11 the Commonwealth could:

(i) reschedule cannabis under the Poisons Standard; and/or

(ii) create a new schedule to allow access to it for use by Victorians participating in medicinal cannabis scheme; and/or alternatively;

(iii) amend and remove cannabis from the operation of the national Therapeutic Goods Administration scheme and/or establish a regime for dealing with cannabis independent of the existing Therapeutic Goods Administration framework; [401]

1.12 the following additional legislation is also applicable to the operation of a medicinal cannabis scheme in Victoria:

- Health Practitioners Registration National Law Act 2009 (Vic) and;
- Food Act 1984 (Vic) incorporating Food Standards Australia New Zealand Code (Cth);

1.13 the following additional Commonwealth legislation is also applicable to operation of a medicinal cannabis scheme in Victoria:

- National Health Act 1953 (Cth);
- Narcotic Drugs Act 1967 (Cth);
- Customs Act 1901 (Cth);
- Customs (Prohibited Imports) Regulations1956 (Cth) and;
- Psychotropic Substances Act 1976 (Cth);

1.14 cannabis flowering tops, resin and leaves are subject to controls under the United Nations Single Convention on Narcotic Drugs 1961 ("The UN Convention"). Cannabis is a prohibited and scheduled drug for the purposes of the Convention. The UN Convention limits the availability of cannabis to be used for medicinal and scientific purposes only. The Convention provides[402]:

- for the medicinal use of cannabis;
- that cannabis is indispensable for relief of pain and suffering; and
- that ''adequate provision'' must be made to ensure cannabis for medicinal use is available ''to relieve pain and suffering;''

1.15 cannabis flowers, cannabis resin (crude or purified), leaves, tinctures and extracts are all subject to special measures of control under the UN Convention. Australia is a signatory to the UN Convention and must comply with the obligations stated in it. Victoria has adopted

the Convention as reflected in legislation such as the Drugs Poisons and Controlled Substance Act 1981 (Vic);

1.16 for the purposes of the Convention, cannabis when separated from the flower is regarded as ''production'' with all other processes regarded as ''manufacture''; [403]

1.17 manufacturing covers a wide range of activity;

1.18 the Narcotics Drugs Act 1967 (Cth) prohibits the ''manufacture'' of narcotics, including cannabis, without a manufacturing license. It appears that individuals participating in a medicinal cannabis scheme in Victoria may require a licence to "manufacture" which would be issued by the Commonwealth. The Act does not expressly bind the State Government of Victoria, but may apply to it. Where this is so, the State Government of Victoria may also require such a license, depending up the degree to which it participated in a medicinal cannabis scheme;

1.19 for the purposes of the UN Convention, If cannabis is to be cultivated one or more Commonwealth Government agencies[404] must be established to:

- license cultivators;
- designate specific areas for cannabis cultivation;
- specify the land and amount of land on which cultivation is permitted; and
- receive cultivated crops from licensed cultivators; [405]

1.20 the UN Convention on Psychotropic Substances 1971 further controls the operation of cannabis, also recognising that it should be made available for medical purposes. This UN Convention forms the basis for the Psychotropic Substances Act 1976 (Cth);

1.21 these Conventions collectively call for the establishment of criminal sanctions associated with any steps in the unauthorised use or availability of cannabis. They also form the basis of the Narcotic Drugs Act 1967 and the Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990 (Cth), as well as the Criminal Code Act 1995 (Cth), prohibiting cultivation, trafficking and manufacturing of cannabis;

1.22 the national Therapeutic Goods Administration schemes also prohibits the manufacture of ''unapproved'' ''therapeutic goods''. Goods that are not registered under the national scheme are regarded as ''unapproved goods''. It is unlawful to import, manufacture or supply these goods in Australia, unless they have been excluded or exempted from the register during the regulatory evaluation process;

1.23 to "manufacture'' under the Therapeutic Goods Administration schemes (''the national therapeutic goods scheme''), includes possessing cannabis plant material and engaging in any part of the process of producing or brining cannabis or a cannabis product to its final state;

2. The question is raised as to whether the national Therapeutic Goods Administration scheme applies to and operates in respect of, the cannabis plant.

It is submitted that:

(i) cannabis is not primarily a ''therapeutic good'' and or a ''medicine'' for the purposes of the national therapeutic goods scheme;

(ii) for present purposes and in reference to cannabis, a good has ‘’therapeutic use’’ when it is used in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in a person;
- influencing, inhibiting or modifying a physiological process in persons; or
- testing the susceptibility of persons to a disease or ailment;

(iii) “medicines” for the purposes of the regulatory scheme are ‘therapeutic goods’’ as defined, that are represented or likely to achieve their intended therapeutic action in or on the body;

(iv) the regulatory scheme only applies to goods that are ‘’therapeutic goods’’, as well as ‘’medicines’’ as defined by the legislation;

(v) “medicines’’ that are governed by the regulatory frame work, are evaluated and are either entered on to a register of approved therapeutic goods (referred to as registered medicines/ therapeutic goods) or a list (referred to as listed medicines/therapeutic goods);

(vi) not all substances are “therapeutic goods’’ or ‘’medicines’’ for the purposes of the regulatory schemes;

(vii) not all substances that have a therapeutic operation on the body are ‘’medicines’’ for the purposes of the regulatory schemes;

(viii) it is acknowledged by the Commonwealth that some substances sit at the regulatory ‘’medicine/food interface,’’ an area in which substances that are ‘’foods’’ are not regarded as ‘’medicines’’ (‘’therapeutic goods’’), even though they may have a therapeutic operation in or on the body. These substances are not governed by the national therapeutic goods regulatory scheme;

(ix) in addition to stating what a ‘’therapeutic good’’ is for the purposes of the regulatory scheme, the definition of a ‘’therapeutic good’’ under the legislation also states what it is not;

(x) a ‘’therapeutic good’’ as defined, does not include substances for which there is an identifiable standard under the Food Standards Australia New Zealand Act 1991 (Cth) (“FSANZ”) or goods which in Australia or New Zealand have a tradition of use as foods for humans in the form in which they are presented;

(xi) this clearly acknowledges that foods that have identifiable standards under the FSANZ are not ‘’therapeutic goods’’, or ‘’medicines’’ and are not administered under the national therapeutic goods regulatory scheme;

(xii) cannabis in the form in which it presents, has a tradition of use as food and has been recognized as a traditional food source for centuries;

(xiii) cannabis sits at the regulatory food/medicine interface;

(xiv) there are FSANZ foods standards applicable to cannabis and are most notable in their current application to high CBD low THC seeds and oil (called ‘’hemp foods’’). Hemp foods and products are derived from the Cannabis Sativa L plant;

(xv) FSANZ Standard 1.4.4. (until recently) prohibited cannabis and or substances derived from cannabis being added to or ‘’sold as food’. Despite this, statements issued by FSANZ in the past have clearly recognise cannabis as a food and more over, a safe food for regulatory purposes;

(xvi) in undertaking a review of an application to amend Standard 1.4.4 the FSANZ Forum stated: ‘’ The Forum noted that FSANZ found that the seeds of low THC hemp and foods derived from them, do not present any safety concerns as ‘’food.’’[406]

(xvii) In 2012 FSANZ approved an amendment to Standard 1.4.4 providing for the sale of cannabis sativa seeds, oil, beverages and other substances extracted from seeds containing low THC ‘’as a food” and/or as an ingredient of food. The variation submitted for the approval of Australian and New Zealand Ministers in January, 2015 (FSANZ Forum) was rejected.

(xviii) it is submitted that cannabis in its raw form (flowers, resin, leaf, stem, seed,) is a nutritious food. It is recognized as such by FSANZ, despite the failure of Australian/New Zealand Ministerial Forum to approve the recommended amendment and issue of an appropriate standard. It appears that Forum’s rejection was not based on the inappropriateness of regarding cannabis as a food. This demonstrates how closely cannabis sits at the regulatory food/medicine interface;[407]

(xix) given the historical use of cannabis as a food, cannabis in its natural has a tradition of use as food amongst multicultural Australians;

(xx) the following are not regarded as medicine’s and/or are not registered medicines under the national therapeutic goods scheme:

- cultivated herbal plants for commercial sale in Victoria;
- herbs and tinctures made up and provided to patients by herbalists and/or naturopaths; and
- products made by compounding pharmacists.

3. Accordingly, it is considered that the national therapeutic goods scheme may not apply to the cannabis plant. Closer consideration should be given to this matter.

4. Cannabis, a natural food and herbal medicinal, cultivated and manufactured by and for patients, exclusively for their own personal use and health needs, should not in any event be subjected to regulatory processes.

5. Consequently, the Victorian Government:

- may not be hampered by the operation of the national therapeutic goods scheme in relation to cannabis;.

- appears to have the ability to amend the Drug Poisons and Controlled Substances Act 1981 (Vic) to allow for individuals to engage in activities such as the cultivation, possession, use, administration, supply and sale of cannabis. In such circumstances, individuals would be provided a defence under the Commonwealth Crimes Code 1995; [408]

- and possibly any individual that participates in a medicinal cannabis scheme in Victoria, may require a manufacturing license to be issued by the Commonwealth under the Narcotic Drugs Act 1961 (Cth);

- might be able to either, enter into an arrangement with the Commonwealth or request the Commonwealth to amend the Narcotic Drugs Act 1967 and or regulations, to exempt those participating in a medicinal cannabis scheme in Victoria from having to hold a manufacturing license and or alternatively, mandate that any Victorian regulatory agency involved in the operation of a medicinal cannabis scheme be permitted to issues such manufacturing licenses for and on behalf of the Commonwealth for the purposes of the scheme;

- and possibly any individual participating in a medicinal cannabis scheme in Victoria may require importation licences. Referring to paragraph 3 and for the purposes of clarity an amendment to the national therapeutic goods legislation might be desirable to make it clear that such does not apply, together any appropriate amendments to the Customs Act and or regulations.

6. The question arises as to whether and or to what extent, the State Government of Victoria might be bound by any other provisions of the UN Conventions not currently embodied in federal and /or Victorian legislation. Art 28 & 28(d) of the Single Convention on Narcotic Drugs 1961 requires the Commonwealth to, amongst other matters, take supply of all cannabis crops cultivated. It is submitted that if the Victorian Government has agreed to adopt and or be bound by such a requirement, that this could limit the nature, scope and operation of a medicinal cannabis scheme in Victoria.

7. The Commonwealth could reschedule cannabis under the current Poisons Standard, creating a new schedule for the use of cannabis in a medicinal cannabis scheme or otherwise exempting the operation of the current Schedule 1 classification applying to cannabis use within the context of a medicinal cannabis scheme.

8. In the alternative, were the state and federal governments to apply the national therapeutic goods legislation to cannabis, the same could be amended to confirm and or reflect:

   (i) that cannabis is exempt from the operation of the legislation and or in the alternative;

(ii) that cannabis and cannabis goods be deemed complimentary medicines and listed goods for the purposes of a medicinal cannabis scheme and that Schedule 14 of the regulations be amended accordingly.

9. This submission does not support the proposal at 7(ii) above, as cannabis is regarded as a plant and a food and as such, it is considered that it should not and is indeed questioned as to whether it can be regulated and processed as a ‘’medicine’’ under the national therapeutic goods schemes. It is not in the interest of Australians to have food reclassified and regulated in this manner.

10. The content of this submission proceeds on the assumption that the national therapeutic goods scheme may not apply to the cannabis plant and/or alternatively, that relevant amendments to the national therapeutic goods scheme, the Narcotic Drugs Act 1961 (Cth), and other relevant legislation could be made with the co-operation of the Commonwealth Government. This would give rise to a medicinal cannabis industry modelling shared powers and responsibilities between the Commonwealth and State in the same manner that gave rise to the Victorian Opium industry.

REGULATORY OBJECTIVES FOR A MEDICINAL CANNABIS SCHEME

1. It is acknowledged and submitted that:

1.1 the terms of reference set down by the government should be acknowledged;

1.2 knowledge about benefits and risks associated with medicinal cannabis is important to ensure patients receive a satisfactory therapeutic outcome without undesirable consequences;

1.3 determining who may have lawful access under a scheme should not be limited to questions of law. Health issues together with the needs and circumstances of potential participants must be considered;

1.4 as many Victorians with a legitimate need should be granted access to cannabis under any proposed scheme;

1.5 use of medicinal cannabis should be supervised as a part of a patients general health program, which be monitored and reviewed periodically;

1.6 information of and informed consent as to risks and benefits of medicinal cannabis use should be given to and by patients under any proposed scheme;

1.7 medicinal cannabis under any proposed scheme must be:

(i) accessible;

(ii) safe for its intended use when distributed commercially to third parties; and

(iii) available in sufficient forms and quantities to assist a wide range of patient medical conditions and needs in order to address pain, suffering and improve quality of life, in the same way other patients are currently accommodated with registered pharmaceutical products;

1.8 a medicinal cannabis scheme must:

(i) ensure all participants in the scheme are free from the threat of legal prosecution and or unlawful discrimination;

(ii) ensure that non commercial entities in the scheme are not met with unnecessarily high and or unreasonable regulatory standards or requirements;

(iii) ensure privacy and patient confidentiality is respected and maintained in the operation of any proposed scheme;

(iv) respect the patients right to make health care choices is maintained and that patients are not prejudiced or denied access to cannabis under any proposed scheme for making such choices;

(v) ensure the general legal and human rights of participants in the scheme are acknowledged and maintained, including but not limited to the following:

- the International Convention on Economic Social and Cultural Rights 1976 that states that everyone has the right to the highest attainable standard of physical and mental health;[409]

- the Charter of Human Rights and Responsibilities Act 2006 (Vic) which includes the right to:

  - equal and effective protection against discrimination (S.8);
  - life and protection of life (S.9);
  - be free from torture, cruel, inhumane or degrading treatment (S.10);
  - privacy (S.13);
  - freedom of thought, conscience, religion and belief (S.14);
  - protection of families and children (S.17);
  - property rights (S.20);
  - liberty and security of the person (S. 21);
  - humane treatment when deprived of liberty (S.22);
  - rights of children in the criminal process (S.23);

- the Australian Charter of HealthCare Rights[410] that provides that individuals have the right to:

  - access the health care needed regardless of their ability to pay;
  - safety: to safe, high quality health care;
  - respect, dignity and consideration, without discrimination;
  - active participation in health care, including the right to refuse treatment;
  - participate in the planning, design and evaluation of healthcare services and systems;
  - privacy regarding your personal and health care information;
  - seek information, provide feedback or make complaints which health care providers should provide and address transparently and fairly;

(vi) ensure quality and content of cannabis distributed commercially should comply with reasonable quality assurance standards;

(vii) ensure that supply, processing and handling, manufacture, distributing, administration and use, be subject to reasonable quality assurance standards and regulations;

(viii) be flexible enough to adapt to meet the changing needs of patients, technological developments, business and science. It must remain relevant over time;

(ix) attempt to strike a balance between competing needs of stakeholders;

(x) sit comfortably within the current legal prohibition framework, without compromising on or forfeiting the proposed objectives and benefits of a scheme;

(xi) sit within the existing legislative and regulatory frame work and be consistent with existing human and civil rights of patients;

(xii) be consistent with successful elements of models adopted in other jurisdictions to ensure an effective utilisation of public resources.

COMMENTS ON REGULATORY OBJECTIVES and TERMS OF REFERENCE

1. The design elements of any proposed medicinal cannabis scheme should reflect:

   - the International Convention on Economic Social and Cultural Rights 1976 which states that everyone has the right to the highest attainable standard of physical and mental health;[411]

   - the Charter of Human Rights and Responsibilities Act 2006 (VIC) which includes the right to:

     - equal and effective protection against discrimination (S.8);
     - life and protection of life (S.9);
     - be free from torture, cruel, inhumane or degrading treatment (S. 10);
     - privacy (S.13);
     - to freedom of thought, conscience, religion and belief (S.14);
     - protection of families and children (S.17);
     - property rights (S.20);
     - liberty and security of the person (S. 21);
     - humane treatment when deprived of liberty (S.22);
     - rights of children in the criminal process (S.23);

   - the Australian Charter of HealthCare Rights[412] that provides that individuals have the right to:

     - access: the health care you need regardless of your ability to pay;
     - safety: to safe high quality health care;
     - respect, dignity and consideration and without discrimination;
     - active participation in health care, including the right to refuse treatment;
     - participate in the planning, design and evaluation of healthcare services and systems;
     - privacy regarding your personal and health care information;
     - seek information, provide feedback or make complaints which health care providers should provide transparently and fairly;

2. The design emphasis should also acknowledge:

   a. the compassionate nature of the scheme, which is inclusionary not exclusionary;

   b. that access to cannabis for medicinal purposes is the exception to the general laws of prohibition expressed in relevant United Nations Conventions and is the ''exceptional circumstance'' for lawful access;

   c. that adequate provision of cannabis be made to ''alleviate pain and suffering'' of Victorians as stated in the UN Single Convention on Narcotic Drugs 1961;

d. that access for such purposes should not be narrowed further or substituted with other criteria's and/or additional stipulations that attempt to do so and/or deny a Victorian who is in pain and or suffering from having access to cannabis;

e. this is not simply a question of domestic law, but is a public health and international human rights issue;

f. this is a health issue firstly and fore mostly and a legal issue secondly;

g. consequently, patient needs, health and general circumstances must be the primary focus, and as such this core focus which should be inserted into a legal frame work. Such needs and considerations in determining lawful access might include, but would not limited to, patients:

- with terminal conditions;
- poor prognosis and / or life threatening conditions that may result in death if not treated;
- rare disease with few or no treatment options;
- excluded from clinical trials;
- who cannot afford conventional treatment options;
- who cannot tolerate other treatment options or have objectives to the same due to risk of side effects and / or possible adverse reactions;
- for whom other treatments have not worked; or
- who have other personal, religious or concerns of conscience.

3. The following comments are made with respect to the Terms of Reference provided to the Commission:

3.1 the intention of the Victorian State Government was to provide terminal and chronically ill Victorians with access to cannabis for medicinal purposes under a compassionate scheme which operated within and subject to, the current laws of prohibition;

3.2 the terms of reference given to the VLRC are not discernably clear. Employment of the term ''exceptional circumstances'' was ambiguous and hence, confusing;

3.3 it is uncertain whether this reference was:

(a) purely descriptive, to distinguish lawful cannabis use in a medicinal rather than a recreational context; or

(b) a key access criteria to be employed in a medicinal cannabis scheme;

3.4. the Commission has proceeded on the basis that it represented a key access criteria to be defined in its scope and operation;

3.5 the approach and the term "exceptional circumstances problematic;

3.6. the Victorian government in the context of, and giving consideration to, the design of a medicinal cannabis system, has provided a key access criteria for lawful cannabis use. In so doing it has:

a. pre-established a design/design framework for a medicinal cannabis scheme;

b. directed design options, influencing outcomes and recommendations to be made by the Commission;

c. lost the opportunity to design features of a system that offer the best possible outcomes, options and recommendations due to a pre-established frame of reference;

3.7 the term “exceptional circumstances’’ It is not a neutral term, but one that implicitly refers to the current laws of prohibition;

3.8 from a system design perspective, failing to use neutral terms can adversely affect stakeholder participation in designing a scheme, as well as outcomes the result from it. The term could justifiably be regarded as inflammatory, by the CCV generally, as well as by medicinal cannabis patients within it. It is a divisive term giving rise to notions of the deserving and undeserving ill. It is therefore likely to cause offense to and amongst Victorian patients and patient groups representing an extensive list of various medical conditions for which cannabis may provide relief;

3.9 as an implicit reference to prohibition it:

a. lends itself to defining the term (and who has lawful access to medicinal cannabis) through a much narrower lens than may otherwise be the case; and

b. frames the approach as a predominantly legal one rather than what it should be, which is a compassionate based design focusing on what would be in the best interests of chronically ill Victorians and then proceeding to work out a possible legal frame work which could support such a model;

3.10 ‘’exceptional circumstances’’ suggests that the circumstances under consideration are uncommon or unusual. A consideration of ‘’all the circumstances’’ is not enough, as the term ‘’exceptional” mandates that consideration must be had to circumstances which when evaluated, those that must stand out from the rest. The term favors circumstances that are: uncommon, remarkable, outstanding or unique. It follows, that many merit worthy circumstances that might otherwise qualify for access may not qualify as ‘’exceptional.’’ The term is therefore an exclusionary term;

3.11 compassion or benevolence, by contrast, involves notions of loving kindness, empathy, concern, fairness, consideration and generosity. Such ideals are inclusionary;

3.12 the core objective of a truly compassionate scheme, may broadly be stated as one that alleviates human suffering and improves the quality of life. As such it cannot, by virtue of its nature, be exclusionary and accept only those circumstances deemed ‘’outstanding ‘’ or ‘’unique” i.e. “exceptional’’. An exclusionary term such as the one employed in the Terms of Reference: “exceptional circumstances’’, which will determine who has lawful access to cannabis, is directly at odds with the essence of a model that is at its heart, inclusionary;

3.13 as a potential lawful access criteria, the term “exceptional circumstances’’ is also unnecessarily narrow;

3.14 this is especially so given that:

- the provisions of the United Nations Single Convention on Narcotic Drugs 1961; &
- that any scheme will be a tightly regulated one;

3.15 Australia is a signatory to the United Nations Single Convention on Narcotic Drugs 1961 (''the Convention''), which it ratified in 1967. Although this Convention declares cannabis a prohibited, controlled and tightly regulated substance, it recognizes its utility and importance to society as a medicinal therapeutic agent;

3.16 the Convention:

- recognizes the medicinal use of cannabis;[413]
- states that it is ''indispensable'' "for the relief of pain and suffering";[414]
- states that ''adequate provision'' of cannabis ''must'' be made available for such purposes;[415]

3.17 the Convention does not place further qualifications or restrictions on the applications associated with its medical use, other than to refer to ''pain and suffering'';

It is submitted that:

a. provision of cannabis for medicinal use is the exception to the general rule of prohibition and its application to address ''pain and suffering'' are the ''exceptional circumstances;''

b. the Convention recognized in 1961 that cannabis for the relief of pain and suffering is ''indispensible''. The term ''indispensible'' implicitly recognizes that cannabis already delivers a efficacious therapeutic benefit to alleviate pain and suffering;

c. the extent to which an efficacious therapeutic benefit must be shown, before lawful access is provided, is therefore questionable;

d. to further limit the noted exception by imposing further limitations i.e. ''exceptional circumstances'' criteria and/or other limitations, must also be questioned; and

e. cannabis should be provided under a compassionate scheme without hesitation where the medical literature supports its use to alleviate pain and suffering in the broadest sense, and it is deemed safe for that patient in all the circumstances. A medical practitioners discretion would determine such and is consistent with their existing professional skills and duty. Where clinical trial evidence is unavailable, doctors should be permitted and/or if not required to use their discretion to consider preclinical studies, general scientific literature, clinical observations or case reports and or clinical N-of1 clinical trials or what is referred to a single patient randomized trial. In fact, medical practitioners should be encouraged to pursue the later.

3.18 to further limit the noted exception by imposing further limitations i.e. ''exceptional circumstances'' criteria and/or other limitations must also be questioned. For

example, to require a patient submit to other treatments before trialling cannabis or that a therapeutic benefits must be shown to be "substantial'' in medical literature before access is provided may be at odds with:

a. domestic and international Human Rights Laws;

b. the notion of compassion, as a compassionate model should funnel as many patients in legitimate need into a scheme rather than narrow the funnel further; and

c. a number of identified Regulatory Objectives for the purposes of designing a medicinal cannabis scheme;

3.19 the appropriate evidentiary evaluation to determine lawful access, which might have been: ''is a patient likely to obtain an efficacious benefit from using cannabis for relief of their pain and/or suffering, in order to justify allowing a patient access to medicinal cannabis?'' could, in view of the wording in the Convention, be reduced simply to: ''does the patient have a medical condition involving pain and / or suffering, which could be alleviated by medicinal cannabis and improve their quality of life?

It is submitted that where it can be shown that:

a. a patient is likely to receive relief from pain or suffering (as recognised by the UN Single Convention on Narcotic Drugs 1961) that would improve the patients quality of life; and

b. the expected relief from pain, suffering and / or an improvement in the patients quality of life outweighs any perceived risk to that patient;

then a patient should be given access to medicinal cannabis under a medicinal cannabis scheme. Further considerations as to efficacy are not required for reasons previously addressed

Such circumstances could be viewed as ''exceptional'' to the general rule of prohibition.

3.20 attempts to define ''exceptional circumstances'' are unwarranted and are not, it is submitted, in line with the nature of:

- the spirit and intent of the UN Convention;
- a compassionate medicinal cannabis scheme; or
- a number of Regulatory Objectives identified for designing a proposed medicinal cannabis scheme. [See: "Regulatory Objectives" and "Comments on Regulatory Objectives and Terms of Reference" in this submission.]

3.21 in contrast to the approach adopted by the Victorian Government in its current Terms of Reference, acknowledge and advocates a collaborative design process involving all key stakeholders where needs are considered and contributions made, and design elements are selected from that process. Such an approach generally results in a higher ''ownership'' of the process amongst stakeholders and is

therefore, more likely to encourage participating in the scheme. A system built upon sensitive issues that is not designed in this manner but is imposed upon concerned parties, is unlikely to be successful, as has been witnessed in other jurisdictions where the unregulated and/or illicit market thrives alongside the imposed medicinal cannabis scheme;

3.22 is noted that whilst the Commission sought to appoint two expert panels: a medical and regulatory advisory panel, it failed to appoint or establish a panel of significant key stakeholders, including one or more members from the CCV. As a result, a disparity may arise between what the Commission might theoretically consider desirable design elements to recommend to the Victorian Government within a legal framework and what in fact, might be useful and likely to be embraced by patients. This disparity may fail to deliver a successful therapeutic outcome for many patients.

4. Whilst this submission has opposed access to medicinal cannabis being determined by reference to ‘’exceptional circumstances” and or doing so, in the manner suggested by the issues paper, this submission supports the Commission’s contention that in assessing who may have lawful access under a scheme should not be limited to questions of law. The needs, health and general circumstances of patients participating in the scheme should also be considered in regard to lawful access considerations. Should the Victorian Government proceed on the basis that lawful access to medicinal cannabis must be provided strictly under ‘’exceptional circumstances’’, then when viewed through a compassionate lens, the following considerations pertaining to a patients circumstances would be relevant. Such might include but not limited to, patients who:

- are terminal or have a poor prognosis for recovery;
- have life threatening conditions;
- have medical conditions that are interfering with their day to day functioning and / or detracting from the quality of their life;
- have rare diseases or illnesses for whom there is no or few treatment options;
- are financially disadvantaged and can not access treatments that are beyond their financial means;
- are denied access to clinical trials for a treatment that might have offered them relief;
- cannot tolerate other treatments or sustain adverse reactions;
- are unwilling to submit to the risks/side effects profile of other treatment options;
- have not obtained satisfactory results from other treatments;
- cannot otherwise access treatments due to physical, geographical, personal, moral, religious or other reasons that raise objections of conscience.

5. The emphasis and repeated references in the issue paper to cannabis spilling over to unauthorised users or the recreational market, is concerning. The primary concern is that an unhealthy emphasis on such could see the design principles employed becoming distorted failing to potentially address the real core issue, which is the health needs and the compassionate operation of a proposed scheme, to relieve pain and suffering and improve the quality of life of Victorians. These core considerations may become unnecessarily

compromised or lost as a result of a primary legal lens. As Aggarwal, S.K. et al in "Dosing Medical Marijuana: Rational Guidelines on Trial in Washington State" make plain: "It is time to value the promotion of heath and quality of life over …legal absurdities.''

6. It is submitted that:

    a. health needs and better health outcomes for terminal and chronically ill Victorians, needs to be the prime focus in designing a compassionate medicinal cannabis scheme;

    b. cannabis being a prohibited substance, whilst acknowledged, needs to be a secondary consideration. A proposed scheme should not be designed from a dominant legal perspective and design lens;

    c. any proposed scheme will be regulatory and will operate within an existing state, federal and international legal framework complete with enforcement remedies and sanctions. A successful design approach would however acknowledge this fact and be careful not to compromise or relegate the needs of patients in favour of law enforcement, for ''fears'' of ''potential'' diversion to unauthorised users and or the recreational market.

    d. the design must:

        - meet the important needs of key stakeholders, particularly patients and their doctors / Medicinal Cannabis Practitioners;
        - be accessible and practical;
        - be functionally competitive with the illicit market (in terms of price, quality, variety and convenience);

        A design that fails to do so, will not be utilized by one or more key stakeholders resulting in:

        - a waste of tax payers funds invested in a resultant scheme;
        - an increased use of the illicit market; and
        - a loss of public confidence in the government's ability to replicate successful models employed overseas.

7. The original Canadian medicinal cannabis scheme offered to Canadian patients by Health Canada was an example of these failings.

8. A dominant legal ''crime and enforcement'' lens and fears concerning diversion of cannabis into the recreational market, were the most likely reasons for the Canadian Government opting for a number of controls, which failed to address the health, needs of Canadian patients operating within the scheme. A state controlled regulatory model offering: limited cannabis strains of poor quality; an inability to inspect and determine whether such strains might be suitable for the patients use[416] due to direct shipping of the product to patients; forcing the participation of medical practitioners to provide medicinal cannabis treatment; and a requirement that patients see a total of three medical practitioners (their general practitioner, as well as two specialists), [417] favoured overly restrictive controls at the expense of the needs of patients. This resulted in patients being unable to access medicinal

cannabis and / or abandoning the scheme, returning to the illicit market. This in turn gave rise to a burgeoning industry of medicinal cannabis Compassion Clubs and Medicinal Cannabis Clinics/dispensaries. The right of dispensaries and Compassion Clubs to operate, has subsequently been acknowledged and upheld by many Canadian government bodies including the Canadian Senate Special Committee on Illegal Drugs, the Ontario Court of Appeal and the British Columbia Provincial Court, stating that they provide a valuable and necessary role in the health care of Canadians.[418] It is submitted that this outcome, was the likely result of approaching the design of a medicinal cannabis system, from a legal dominated lens rather than a health and or compassionate one.

PART FIVE

PROPOSED MODELS FOR A MEDICINAL CANNABIS SCHEME

PROPOSED MODELS FOR A MEDICINAL CANNABIS SCHEME

1. There are a number of design options that can be considered for adoption in a medicinal cannabis model for Victoria.

   Eight countries currently provide access to botanical cannabis for medicinal purposes, which includes 35 states of the USA (together with the District of Columbia and Guam), Canada, Israel, Italy, Germany, Finland, the Netherlands as well as the Czech Republic. Pharmaceutical cannabis extracts are also available. Nabiximol is a registered pharmaceutical in Australia as well as Canada, New Zealand, UK, Austria and Czech Republic, with other synthetic pharmaceutical cannabis extracts available in the following eight countries: USA, UK, Canada, Austria, France, Germany, Spain and Switzerland.

2. A number of these countries provide access to medicinal cannabis under a variety of regulatory models. These models seek to:

   - distinguish between medicinal and recreational use;
   - maintain control over production and distribution;
   - control or limit the product a patient can access.

   The reasons for doing so are to:

   - prevent diversion to non authorised users;
   - safety: to control the psychoactive form of the plant;
   - product quality and control.

3. Models can be distinguished from one another on the basis of:

   - providing a defence for the use of medicinal cannabis;
   - government controlling supply and distribution;
   - government regulating supply and distribution.

PROVIDING A DEFENCE FOR MEDICINAL CANNABIS USE

1. This proposals advocates amending state and federal legislation to provide persons with a legal defence associated with the possession and use of cannabis for medicinal purposes, as a single solution towards assisting ill and terminal patient patients in need. Provision of a defence would not however, afford such Victorians, their carers and compassionate cannabis suppliers, protection from legal process. It also fails to address a number of legal and non legal issues associated with the supply of cannabis in those circumstances.

A GOVERNMENT CONTROLLED MODEL

1. The Netherlands currently operates a government controlled medicinal cannabis program. Through a regulated government body known as “The Office of Medicinal Cannabis” the Netherland controls:

   - licensing of cultivation;
   - the form of cannabis permitted to be supplied (dry plant material only);
   - supply;
   - distribution (including- dispensing, import/export);

- quality control;
- product labelling;
- price.

The Canadian medicinal cannabis scheme initially implemented by Health Canada, was also similar, in its operation to the Netherlands model at its inception.

A GOVERNMENT REGULATED MODEL

1. A government regulatory model is favoured by this submission. This particular model involves the establishment of a state agency regulating the vertical supply and distribution of medicinal cannabis, cannabis products and services involving the following registered and or licensed participants operating within the scheme:

    - State Government agency or department(s);
    - patients, parents, guardians, carers;
    - General Medical Practitioners or Medicinal Cannabis Practitioners;
    - Medicinal Cannabis Dispensary practitioners;
    - Medicinal Cannabis Dispensaries;
    - Compassion Clubs or Co-operatives;
    - Cultivators of cannabis for medicinal use;
    - Manufacturers of medicinal cannabis products.

2. The relevant state government agency or departments may control supply and distribution of medicinal cannabis directly by:

    a. permitting lawful cannabis possession, use and or administration for eligible registered patients, parents, guardians and or their carers;
    b. regulating the cultivation, processing, supply and sale of medicinal cannabis under license;
    c. regulating the issue, modification, renewal, suspension and revocation of licenses and licensing requirements;
    d. monitoring compliance with regulatory requirements by those participating in the scheme;
    e. monitoring the quantity of cannabis in circulation in the community to avoid diversion to the illicit market;
    f. providing a dispute resolution and/or appeals process; and
    g. education program for the participants under the scheme and general community.

SUPPLY UNDER A GOVERNMENT REGULATED MODEL

CULTIVATION

It is acknowledged and/or submitted that:

1. under this model cultivators apply for licenses to supply a variety of cannabis strains to:

   (i) a state agency; and/or
   (ii) third parties such as Medicinal Cannabis Dispensaries, Compassion Clubs and manufacturer's of cannabis goods;

2. commercial cultivation licenses in overseas jurisdictions are heavily regulated to safeguard against diversion to the illicit market;

3. applicants must satisfy stringent criteria to obtain and retain licences which are generally issued via competitive processes, with the number of licenses being limited to ensure that the supply of cannabis does not exceed the quantity of cannabis required for therapeutic purposes leading to a surplus and the potential for diversion to the illicit market;

4. financial barriers associated with cultivating cannabis also reduce the number of licenses granted to cultivators. Stringent regulatory requirements and license fees ($100,000-$300,000), legal and consulting fees ($30,000-$100,000), land and cultivation set up costs (well in excess of $500,000)[419] also keep entry levels and the number of commercial licenses issued under medicinal cannabis schemes relatively low. For example, Health Canada has issued a total of 23 cultivation licenses under its medicinal cannabis program;

5. patients may also apply for personal licenses to cultivate under a "Personal Production License" ("PPL") or nominate a third party to cultivate a specified number of plants on their behalf, under licenses referred to as ''Designated Production Licenses''("DPL"). PPL and DPL's are considered an essential part of medicinal cannabis schemes in operation in overseas jurisdictions because they enable a patient to have access to cannabis medicine which they might otherwise be denied due to physical, geographical, health or financial barriers;

6. some jurisdictions that allow patients to produce their own cannabis under PPL's permit patients to grow indoors or outdoors and or a combination of both. Under the medicinal cannabis program in Canada, patients are permitted to cultivate cannabis either indoors or outdoors or in combination, with one outdoor crop per year and up to three indoor crops per year[420];

7. the quantity of cannabis a patient under a PPL or a DPL can cultivate, is determined by licensing conditions which stipulate the number of seeds, clones, propagated juveniles ("trailing plants" for further continuous cultivation purposes) and plants permitted to be produced at any one time. Some jurisdictions specify a uniform number of plants. In the USA this varies from 10 to 15 plants[421], although scientists[422] have called for legislative amendments to allow patients to cultivate up to100 plants to address the medicinal need of some patients. Medicinal need was the focus of the Canadian medicinal cannabis program, where the number of plants that a patient was permitted to cultivate or have grown on their behalf was calculated to ensure a patient had sufficient medicinal cannabis to meet their

daily medication requirements.[423] The calculation was also applied to determine the quantity of cannabis that would be yielded from the number of plants a patients was permitted to cultivate which would represent the total quantity of cannabis a patient would be permitted to have in their possession. This calculation was expressed as a storage quota[424]. Cannabis in excess of the storage quota was required to be destroyed[425]. Health Canada has tried unsuccessfully to abolish this aspect of the Canadian medicinal cannabis scheme[426];

8. third parties holding a DPL in overseas jurisdictions are generally limited to the number of patients for whom they can grow cannabis for, at any one time. The Canadian medicinal cannabis program currently limits that number to 3 patients, however recent submissions prepared by the Medicinal Cannabis Patients Alliance of Canada Inc., are currently seeking to this number increased from 3 to 5 patients[427];

9. to assist regulators in monitoring supply and catering to demand, some jurisdictions require patients to register with a commercial producer. Health Canada, electing to bypass a Medicinal Cannabis Dispensary model, requires a patient to nominate a licensed producer. It appears that Health Canada saw this as a way of regulating and dispensing supply. Unfortunately, limited cannabis strains, patients general inability to find a licensed producer to register with to obtain their supply of cannabis from and poor quality cannabis, saw the rise of unregulated Medicinal Cannabis Dispensaries to address theses shortcomings.

PROCESSING AND DISTRIBUTION UNDER A GOVERNMENT REGULATED MODEL

A MEDICINAL CANNABIS DISPENSARY

It is acknowledged and/or submitted that:

1. Medicinal Cannabis Dispensaries fulfil an important and essential role in a successful medicinal cannabis scheme. So much so, that they have arisen in jurisdictions which had failed to provide for such within the operation of their models. (i.e. Canada and the Netherlands coffee shops) Dispensaries may operate as:
    a. a stand alone business operation; or
    b. in addition to commercial cultivation operations; or
    c. as a part of a Medicinal Cannabis Clinic or Compassion Club or Co-operative.

2. although a dispensary performs functions similar to a pharmacy in dispensing cannabis to fill a patient's medicinal cannabis prescription, its role and function is far more extensive.

3. Medicinal Cannabis Dispensaries:

    - provide health care services to the patient and assist patients in achieving therapeutic outcomes;

    - educate and assist patients in selecting appropriate cannabis strains and or products, with appropriate cannabinoids, cannabinoid concentrations / ratios, and terpenes, for specific therapeutic needs and or desired outcomes;

    - advise on:

- risks;
- benefits;
- contra indications;
- how to address any undesired effects of cannabis use;
- dosage;
- application methods; and
- safe use.

- Dispensaries also operate as a liaison point between the patient, their General Medical Practitioners or Medicinal Cannabis Practitioner; monitor prescriptions and patient progress and use of medicinal cannabis under prescriptions as well as acting as a regulatory ''gate keeper' by noting and acting upon any possible supply/diversion to the illicit market;

- regulate the supply of different strains of cannabis by providing feedback to commercial producers based on sales associated to a variety of strains filled under prescriptions;

- regulate the production and quality of medicinal cannabis/cannabis products by requesting:

  - cultivators to supply product at particularly high standards;
  - cultivators to supply organically grown cannabis and/or use cannabis and cannabis products which have had limited applications of chemicals or pesticides;
  - laboratory analysis and the delivery of laboratory test results relevant to each quantity of cannabis or cannabis product supplied;
  - commercial producers and manufacturers of cannabis goods provide higher quality, smaller well defined portion sizes, packaging and specific labelling data and instructions to promote easy and safe patient use and dosage,

4. Medicinal Cannabis Dispensaries hold a variety of cannabis strains, cannabis edibles, apparatus and information all designed to assist a patient in obtaining optimal therapeutic outcomes. They are limited to supplying such to medicinal cannabis patients only. The location and activities of Medicinal Cannabis Dispensaries in overseas jurisdictions are subject to regulation;

5. Medicinal Cannabis Dispensaries may be part of a Medical Cannabis Clinic and or Compassion Club and as such, provide patients and the general community with much needed services. Medicinal Cannabis Dispensaries although omitted as a part of the Health Canada medicinal cannabis scheme, arose independently of it in response to a general community need. The Canadian judiciary has also acknowledged their importance in this regard and has sanctioned the operation of Medicinal Cannabis Dispensaries in Canada, as providing essential health services to Canadians;

6. some Medicinal Cannabis Dispensary models operating in overseas jurisdictions also hold cultivation licenses. In such circumstances, the Medicinal Cannabis Dispensary is often an

extension of that business operating on the same or separate premises as the cultivation site, depending upon the specific laws of the jurisdiction.

MEDICINAL CANNABIS CLINIC / DISPENSARY & COMPASSION CLUB

It is acknowledged and/or submitted that:

1. a Medicinal Cannabis Clinic ('clinic") can under various schemes, operate with or without a licensed dispensary and may take the form of:

    a. a Medicinal Cannabis Clinic as a stand alone business operation; or
    b. a Medicinal Cannabis Clinic as a part of a general medical practice; or
    c. a Medicinal Cannabis Clinic as a part of a Compassion Club or Co-operative.

2. a Medicinal Cannabis Clinic (operating with or without a dispensary) are in some jurisdictions authorised under license to possess, use, administer, supply, sell and or treat patients using medicinal cannabis;

3. Medicinal Cannabis Clinics provide a number of functions and services to the patient, medical profession and community. These include but are not limited to:

    - treatment of the patient with medicinal cannabis;
    - educating patients on cannabis and safe use;
    - educating patients on applications and safe use;
    - monitoring patients use and follow up treatment;
    - organising other social services and general support services for patients;
    - monitoring and supporting fragile patients to ensure that they have assistance with their medicinal cannabis use;
    - general community education and awareness raising;
    - engaging and assisting in scientific research; and
    - facilitate in the regulation of a medicinal cannabis scheme;

    and when operating a Medicinal Cannabis Dispensary:

    - dispense cannabis and cannabis products from a limited number of ''qualified'' or carefully selected licensed producers/manufacturers; and or
    - produce and making their own cannabis products under a manufacturing license and dispense the same to patients; and
    - providing patients with apparatus to use cannabis safely;

4. in addition to providing medicinal cannabis, these clinics may offer and dispense a combination of the following:

- other dried herbs and/or supplements;
- allied health and therapeutic modalities i.e. chiropractor, craniosarcal therapy, acupuncture, physiotherapy, remedial massage, reiki, yoga, counselling, nutrition and dietary advice.

5. Medicinal Cannabis Clinics may also operate within the framework of a Compassion Club or Co-operative.

COMPASSION CLUBS / CO-OPERATIVES

It is acknowledged and/or submitted that:

1. Compassion Clubs or Co-operatives may be incorporated or unincorporated associations who's members are registered medicinal cannabis patients under a medicinal cannabis scheme;

2. members of the Compassion Club or Co-operative join the club for an annual membership fee and come together sharing skills and resources to cultivate, distribute and or manufacture cannabis and cannabis products in accordance with a clubs constitution, rules and or regulations. Patients have access to a wide variety of cannabis strains, products and services, at prices lower than those offered by retail Medicinal Cannabis Dispensaries and /or other licensed operators under the scheme;

3. a Compassion Club or Co-operative has the ability to identify and cultivate a number of popular strains of cannabis (usually by way of third party cultivators holding ''Designated Production Licenses") or can buy in bulk from licensed cultivators and dispense them to patient members at more competitive prices;

4. a successful model of a Medicinal Cannabis Clinic/dispensary and Compassion Club is the British Columbia Compassion Club Society in Vancouver, British Columbia, Canada. It is an incorporated association with an elected Board of Directors and has contractual arrangements with a few cannabis producers carefully selected to supply medicinal cannabis exclusively to the club. The club screens and choses its producers on the basis of their sites, cultivation, curing techniques and skills. The club also enters into agreements with the producers to provide cannabis in a manner and quality that meets the clubs quality assurance standards. Inspections to ensure compliance and batch testing at laboratories for the presence of chemicals, fungi, mould, bacteria, plant components and cannabinoid potency are performed by the club before being distributed amongst members;

5. there are approximately 103 Compassion Clubs that currently operate as Medicinal Cannabis Clinics with a dispensary, in Canada today, modelled on the British Columbia Compassion Club Society model.[428]. The clinics/dispensaries operating out of the Compassion Clubs, are professionally certified/accredited by operations such as the Canadian Association of Medicinal Cannabis Dispensaries. In the USA consultancy services are also available to clubs, clinics and dispensaries to provide guidance on risk management and regulatory compliance issues, as well as accreditation and educational training services[429];

6. Compassion Clubs enable financially disadvantaged patients and/or those who are not physically able or otherwise in a position to grow their own medicinal cannabis, to have

access to and more control over, the type and quality of cannabis they require to meet their sometimes very specific and or complex medicinal needs;

MANUFACTURERS

It is acknowledged and/or submitted that:

1. manufacturers of cannabis products, are licensed by a state agency to possess, use, manufacture, sell and supply medicinal cannabis for topical, oral or suppository use, together with edible foods and drinks exclusively to authorised licensed Medicinal Cannabis Dispensaries;

2. these products are not novelty products for general consumption but are medicinal products and are sold strictly and exclusively to authorised patients participating in medicinal cannabis schemes;

3. they abide by regulatory standards applicable to both the food manufacturing industry, as well as those proscribed by the medicinal cannabis scheme in regard to dose, labelling, advertising and supply;

4. some manufacturers also hold licenses to cultivate and operate both functions from the one location.

AN OVERVIEW OF A PROPOSED MEDICINAL CANNABIS SCHEME FOR VICTORIA

AN OVERVIEW OF A PROPOSED MEDICINAL CANNABIS SCHEME FOR VICTORIA.

1. A regulatory framework for a medicinal cannabis scheme is necessary to give effect to the stated Regulatory Objectives referred to in this submission.

2. The Victorian Government may require the assistance in part, of the Commonwealth Government in the creation of such a framework.

3. The Victorian Government could administer the regulatory framework under its existing government departments or under a statutory body created for such a purpose.

4. It is submitted that it is considered that the national therapeutic goods scheme applies does not apply to the cannabis plant. The Commission is referred to "Regulatory Framework for a Medicinal Cannabis Scheme" as a part of this submission.

5. The medicinal cannabis scheme advocated for the purposes of the submission is framed on the basis of:

   - the matters referred to at paragraph 1 and 4 with relevant amendments to the Drugs Poisons and Controlled Substances Act 1981 (Vic); and

   - that a co operative arrangement can be reached between the Commonwealth and Victorian Government to attend to the necessary amendments of various legislation, including the Narcotic Drugs Act 1967 (Cth) and reach any necessary co-operative agreements, similar to that currently in operation in relation to the Victorian opium scheme.

6. The medicinal cannabis scheme favoured by this submission is a vertical model consisting of:

   a) a Victorian Government regulatory body;

   b) registered and licensed Medicinal Cannabis Practitioners;

   c) registered and licensed Medicinal Cannabis Clinics;

   d) registered and licensed Medicinal Cannabis Dispensaries;

   e) registered and licensed Medicinal Cannabis Dispensary practitioners;

   f) registered and licensed Compassionate Clubs / Co – operative;

   g) registered and licensed cultivators operating under personal, delegated and commercial licenses;

   h) registered and licensed manufacturers of cannabis goods.

7. This submission supports the following proposals.

7.1 The relevant Victorian Government agency or department(s) appointed for the purposes of administering the scheme would maintaining an electronic database to assist in:

a. the supply and distribution of medicinal cannabis via licensing arrangements;
b. issuing, amending, renewing, suspending or revoking licenses;
c. prescribing medicinal cannabis;
d. housing, cross referencing and processing all data relevant to the scheme for:
   - operational purposes;
   - regulatory and compliance purposes; and
   - monitoring possession and supply of cannabis to deter diversion to the illicit market;
e. regulating and improving the medicinal cannabis scheme and assisting towards scientific development and research.

7.2 The database would be accessible (in part) to the following participants under the scheme:

- General Medical Practitioners and hospitals;
- Medicinal Cannabis Practitioners;
- Medicinal Cannabis Dispensaries Practitioners; and
- Law Enforcement Officers;

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7.3 Health care professionals would access the electronic database using their AHPRA and/or other registration number issued to them for the purposes of the scheme.

7.4 All General Medical Practitioner's and selected allied health professionals, referred to as ''Medicinal Cannabis Practitioners,'' would be registered and licensed under the scheme using their AHPRA codes. Medicinal Cannabis Practitioners would use their professional discretion to determine if a patient should be treated with medicinal cannabis.

7.5 Medicinal Cannabis Practitioners for the purposes of the scheme could include one or more of the following health professionals:

- General medical practitioner;
- Pharmacists;
- Chiropractor;
- Dentist;
- Registered nurse;
- Herbalist; / or
- Naturopath.

7.6 General Medical Practitioners or Medicinal Cannabis Practitioners would complete and issue a ''certification" stating that a patient meets the regulatory access criteria for the lawful use of medicinal cannabis under the scheme.

7.7 A General Medical Practitioner or Medicinal Cannabis Practitioner would formulate a treatment plan for the patient's use of medicinal cannabis. The treatment plan would set out amongst other matters.

- the proposed term of treatment up to a period of 12 months. This period would accord with the duration and validity of the certification process and prescriptions and the licenses issued under the scheme; and

- Particulars of the patients required Maximum Total Daily Dose ("MTDD") and/or a patients Total Daily Dose (where that patient is titrating up to the maximum daily dose of medicinal cannabis); and

these details would be provided to the relevant Victorian Government agency or department.

7.8 For the purposes of the scheme a certification would be valid for 12 months and evidenced by either:

(i) the activation of a treatment plan in the form of the issue and filling of one or more prescriptions in the same period and/or

(ii) the issue of one or more cultivation licenses within the same time frame.

7.9 General medicinal practitioners or Medicinal Cannabis Practitioners could operate out of a Medicinal Cannabis Clinic.

7.10 Medicinal Cannabis Clinics would be licensed clinics that could operate:

- as a stand alone clinic; or
- with a licensed dispensary; or
- with a licensed dispensary as a part of a registered Compassion Club.

7.11 A Medicinal Cannabis Clinic would:

- employ registered and licensed General Medical Practitioners or Medicinal Cannabis Practitioners;
- determine whether a patient meets the lawful access criteria for entry into a medicinal cannabis scheme; and
- certify that it is appropriate for the patient to be prescribed medicinal cannabis under the scheme;
- issue a medicinal cannabis treatment plan;
- provide the patients Maximum Total Daily Dose of medication from the medicinal cannabis treatment plan, with the relevant Victorian Government agency or department and proceed to treat and prescribe medicinal cannabis for the patient;
- provide cannabis information and education;
- advise of safe and proper use of medicinal cannabis;
- provide ancillary therapeutic treatments and services;
- provide regulatory checks and balances.

7.12 The certification and a patients Maximum Total Daily Dose of medicinal cannabis as provide to the Victorian Government, would be required for:

- the issue of a Medicinal Cannabis Card and all cultivation licenses issued for the purposes of the scheme;
- determining the quantity of medicinal cannabis a patient could have in their possession at any one point in time under prescription and/or licenses issued under the scheme;
- assisting the Victorian Government to determine the quantity of cannabis that can be cultivated by commercial cultivators across Victoria in a 12 month period; and
- prescribing and dispensing medicinal cannabis or the purposes of the scheme.

7.13 Patients, parents, guardians and carers requiring medicinal cannabis would make application to the relevant Victorian Government agency or department established to administer the scheme for appropriate Victorian and Commonwealth licenses. These licenses would issue simultaneously in the form of a Medicinal Cannabis Card.

7.14 The issue of a Medicinal Cannabis Card would, in and of itself, constitute a license to possess, use, manufacture, administer and/or supply cannabis by/or for a patients use and medicinal needs;

This is referred to for the purposes of this submission as an “Authority to Possess License” or “APL.”

7.15 An APL or a Medicinal Cannabis Card would authorise a holder to obtain and possess medicinal cannabis and cannabis products on prescription dispensed by a registered and licensed Medicinal Cannabis Dispensary Practitioner at a Medicinal Cannabis Dispensary.

Additional licenses under the scheme that might also be held by a patient, parent, guardian or carer, would be noted on a Medicinal Cannabis Card signifying the nature of the license(s), held.

7.16 It is proposed that:

A Medicinal Cannabis Card would also be used to:

- obtain a prescription for medicinal cannabis;
- have a prescription filled for medicinal cannabis and or cannabis products at a Medicinal Cannabis Dispensary;
- join a medicinal cannabis Compassionate Club or Co-operative;
- apply for additional licenses, (where required) if the same are not issued at the time of applying for an APL/ Medicinal Cannabis Card;
- identify a card holder as a registered lawful participant under the scheme;
- demonstrate evidence of lawful authority to access, possess, manufacture, administer, cultivate, supply and/or sell cannabis for medicinal purposes, removing the threat of legal process and prosecution. Such would be deemed

to take effect upon issue of the Medicinal Cannabis Card with the appropriate license(s) reference(s) embedded on the card.

7.17 A Medicinal Cannabis Card would be valid for a period of 12 months. This would enable:

- regulators to assess demand for commercially cultivated cannabis under commercial production licenses by having applicants for Medicinal Cannabis Cards specify the nature of the license(s) they require on making their application for a card under the scheme;
- a review of a patients treatment plan;
- uniformity regarding the duration and operation of an APL and or other licenses with that for a valid certification and/or a prescription for the purposes of the scheme;

7.18 Medicinal Cannabis in all its forms would be available on prescription to all patients holding a valid Medicinal Cannabis Card.

7.19 All registered General Medicinal Practitioners and Medicinal Cannabis Practitioners would be given prescribing rights for the purposes of the scheme.

7.20 Medicinal cannabis and cannabis products would be made available to patients under a valid prescription by either a General Medical Practitioner or a Medicinal Cannabis Practitioner.

7.21 Prescriptions would be completed by these practitioners online by accessing the electronic database operated by the Victorian Government for the purposes of the scheme. A copy would be printed and provided to a patient.

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7.22 Prescriptions would be dispensed by a registered and licensed Medicinal Cannabis Dispensary Practitioners at a licensed Medicinal Cannabis Dispensary.

7.23 Licensed Medicinal Cannabis Dispensary Practitioners for the purposes of the scheme could be one or more of the health care professionals identified at paragraph 7.5 above.

7.24 Medicinal Cannabis Dispensary Practitioners would have access to the electronic database using their AHPRA and or other registration number issued to them for the purposes of the scheme, in order to assess and fill prescriptions for medicinal cannabis.

7.25 Medicinal Cannabis Dispensaries would be registered and operate under licenses issued by the relevant Victorian Government agency or department and may operate as a:

- stand alone operation; or
- a part of a Medicinal Cannabis Clinic; or as
- a part of a Compassion Club / Co –Operative;
- Medicinal Cannabis Clinic within a Compassion Club or Co-Operative;

7.26 A Medicinal Cannabis Dispensary would dispense cannabis and cannabis products supplied by licensed cultivators and manufacturers. Cannabis and cannabis products supplied will have been:

- tracked from third party cultivators from ''seed to point of sale'';
- batched tested by commercially accredited laboratories issuing reports on cannabinoid content and potency as well as the general quality of the cannabis;
- sealed in clearly identified batch numbered, sterile tamper proof/tamper evident bags;
- sealed in tamper proof/tamper evident food grade packaging with clear labelling distinguishing it as a medicinal product with reference to specific cannabinoid data and content per serving portion, for easy dosage purposes;

7.27 A Medicinal Cannabis Dispensary Practitioner would dispense cannabis and cannabis products strictly to participants holding a valid Medicinal Cannabis Card and in accordance with the operation of a valid prescription and the conditions of the license(s) held.

7.28 A licensed Medicinal Cannabis Dispensary Practitioner would monitor a patients use and the quantity of cannabis distributed to a patient over a prescription period.

7.29 A licensed Medicinal Cannabis Dispensary Practitioner would limit the quantity of medicinal cannabis dispensed up to a patients Maximum Total Daily Dose of Cannabis ("MTDD") over the duration of the prescription period (i.e. MTDD =10 grams a day x 30 days =300 grams a month) in a percentage distribution in accordance with the terms of any license(s) held by the patient.

7.30 Patients could have their prescriptions filled up to the limit set out under their licenses by registering with one or more Medicinal Cannabis Dispensaries.

7.31 A Medicinal Cannabis Dispensing Practitioner would be given a discretion to limit the quantity of medicinal cannabis dispensed under a prescription where the patients health and well being was consider at risk and/or where there are legitimate concerns of unauthorised use or illegality.

7.32 Medicinal Cannabis Dispensaries would operate strictly on an appointment basis. After an initial consultation patients registered with a Medicinal Cannabis Dispensary could elect to have their prescriptions filled via telephone, online ordering and discrete postal delivery. This would provide an important service especially for the elderly, infirm, housebound, disabled or regional Victorian patients.

7.33 Medicinal Cannabis Dispensaries could provide storage facilities for cannabis cultivated by or on behalf of patients (where desired), for a nominal fee.

7.34 Supplies of medicinal cannabis would be generated under licenses issued by the relevant Victorian Government agency or department to:

a. patients cultivating cannabis under a "Personal Production License" or "PPL";

b. patients engaging a third party to cultivate cannabis under a "Designated Production License" or "DPL". A license issued to the patient to engage the third party to cultivate cannabis on their behalf would be an "Authority to Designate Production under License" or a "DPL (A).""

c. a Compassion Club or Co-Operative in the form of a DPL (A) to engage third parties holding a DPL to grow cannabis for the collective benefit of its patient membership.

d. commercial producers cultivating cannabis under a "Commercial Production License" or "CPL" to supply Medicinal Cannabis Dispensaries or under a DPL to supply a patients holding DPL (A)'s.

7.35 In addition to the authorization conferred by an Authority to Possess license or APL in the form of a Medicinal Cannabis Card, a participant of the scheme may also require and could also apply for one or more of the following licenses:

(i) a "Personal Production License" or "PPL"; and/or

(ii) an "Authority to Designate Production under License" to a third party or "DPL (A)" to appoint an:

- individual;
- Compassion Club or Co-Operative or
- Commercial producer; or
- a combination thereof

to grow cannabis under an "Designated Production License: ("DPL") up to the quantity permitted under the terms of the license.

7.36 In making an application for a license under the scheme a patient would specify:

(i) what licences are required (if any) by the patient in addition to an Authority to Possess License issued in the form of a Medicinal Cannabis Card; and

(ii) what percentages of their Maximum ("MTDD") of medicinal cannabis is to be supplied across the licenses held by the patient and over what period of time.

7.37 By way of example a patient might stipulate on their application for a Medicinal Cannabis Card that:

a. 100% of MTDD of medicinal cannabis to be acquired on prescription under a APL via Medicinal Cannabis Dispensaries over a 12 month period; or

b. 100% of MTDD of medicinal cannabis is to be acquired on prescription under a DPL (A) via a Compassion Club with a dispensary over a 12 month period;

c. 50% of MTDD of medicinal cannabis is to be acquired under a PPL (over an 8 month period allowing 4 months cultivation & post cultivation processing) and 100% on prescription under a APL via a Medicinal Cannabis Dispensary over 4 month cultivation period, and thereafter 50% over the 8 month period.

d. 50% of MTDD of medicinal cannabis is to be acquired under a PPL (over an 8

month period allowing 4 months cultivation & post cultivation processing), 100% on prescription under a APL for 4 months and thereafter, 25% on prescription under a APL and 25% from another source i.e DPL(A) over the remaining 8 month period.

7.38 Under a PPL a patient may cultivate and harvest:

- a specified number of seeds, clones or propagated juvenile's ("trailing plants" for continuous cultivation purposes) and flowering plants;
- indoors, outdoors or a combination thereof (but not simultaneously) over a 12 month period or any part thereof;
- the yield from that crop up to a calculated quantity identified as the license holders "permitted storage quota"; or
- have cannabis (or any part thereof) stored at a Medicinal Cannabis Dispensary and may either;
- sell any unexpected crop excess over the patients permitted storage quota to:
    - a Medicinal Cannabis Dispensary; or
    - donate it to a nominated Compassion Club or Co-Operative; or
    - otherwise destroy or deal with it under any regulations.

7.39 A patient, parent, guardian or carer, holding such a license would be required to keep certain records and registers (i.e. horticultural register) and submit to crop and site inspections by a Local Municipal Council.

7.40 Under the terms of a DPL (A) a patient, parent, guardian or carer, may have the third party cultivate and harvest:

a. a specified number of seeds, clones, propagated juvenile ("trailing plants" for continuous cultivation purposes) and flowering plants;

b. indoors, outdoors or a combination thereof (but not simultaneously) over a 12 month period or any part thereof; and

c. where cultivation occurs via a Compassion Club or Co-Operative, the patient may receive a variety of strains of cannabis under a valid prescription, pooled from a variety of crops grown on behalf of club members up to a patients permitted storage quota set out under the terms of the patients DPL (A); or

d. where the crop is cultivated by an individual or a commercial producer, the patient may:

    - take delivery of the crop up to the patients permitted storage quota as set out under the terms of the DPL(A); and/or
    - direct that the same be stored at a Medicinal Cannabis Dispensary for safe keeping and dispensing; and/or
    - direct that any unexpected crop excess over the patients licensed

permitted storage quota be:

- Sold to a Medicinal Cannabis Dispensary (in lieu of storage fees); or
- donated it to a nominated Compassion Club or Co-Operative; or
- otherwise destroyed or deal with under any regulations.

7.41 A patient would be permitted to cultivate:

(i) up to 3 indoor grows per year with a limited storage quota set out under the terms of a patients license; or

(ii) up to 2 indoor and 1 outdoor cultivation (but not simultaneously) over a 12 month period up to a patients limited storage quota, set out in the terms of the patients license.

7.42 The total quantity of medicinal cannabis that can be possessed and controlled by a patient, parent, guardian or carer at any one time would be:

a. upon the issue of a Medicinal Cannabis Card or APL:

(i) the patients Maximum Total Daily Dose ("MTDD") over the duration of the prescriptions period; (i.e. the patients MTDD =10 grams x the prescription period = 30 days =300 grams); or

(ii) where the MTDD is spread across other licenses held, the percentage of the patients MTDD allocated under the terms of the APL to be filled under prescriptions.

b. under a Personal Production License:

(i) the crop yield to be stored as a 'permitted storage quota'' set out under the terms of the license; and

(ii) the total number of plants and flowering plants permitted to be cultivated and harvested under the license using a mathematical formula similar to the one employed by Health Canada under the Canadian medicinal cannabis program, with reference to:

- the patients Maximum Total Daily Dose ("MTDD") of medication;
- the medication period required;
- a deemed yield per flowering plant (30 grams per plant indoor and 250 grams per flowering plant for outdoor cultivation);
- the number of growing periods;
- a percentage to allow propagated juvenile or trailing plants as well as for male/non flowering plants and plant deaths;

(iii) where cultivation is entirely outdoors, the calculation allows for two years of medication to compensate for a possible poor cultivation season in the following 12 months. The permitted storage quota

allows for the storage of 24 months of medicinal cannabis.

c. under a DPL (A) where an individual or commercial producer cultivates cannabis under a DPL:

(i) the crop yield to be stored as a "permitted storage quota" set out under the terms of the license;

(ii) the total number of plants and flowering plants permitted to be cultivated under the license using a mathematical formula similar to the one employed by Health Canada under the Canadian medicinal cannabis program, with reference to:

- the patients Maximum Total Daily Dose ("MTDD");
- the medication period required;
- a deemed yield per flowering plant (30 grams per plant indoor and 250 grams per flowering plant for outdoor cultivation);
- the number of growing periods
- a percentage to allow propagated juvenile or trailing plants as well as for male/non flowering plants and plant deaths.

d. Under a DPL (A) where an individual or commercial producer engaged by a Compassion Club cultivates cannabis under a DPL:

(i) in addition to (c) above, the patient takes their medicinal cannabis dispensed by the Compassion Club up to their permitted storage quota under prescriptions dispensed under the term of their APL via the Compassion Club dispensary.

7.43 parties cultivating medicinal cannabis for patients under DPL's may include:

(i) individuals cultivating for up to a maximum of 5 patients;

(ii) Compassionate Clubs holding an DPL (A) who contract cultivators holding DPLs to supply patient/club members with cannabis from that process;

(iii) Commercial producers with a dispensary operation.

7.44 cannabis may be cultivated for commercial supply by applying for a "Commercial Production License" ("CPL") to the relevant Victorian Government agency or department(s) responsible for administering the scheme, which could be operated as a:

(i) stand alone business; or

(ii) with a dispensary; or

(iii) with a manufacturing operation; or

(iv) with a manufacturing and dispensary operation.

7.45 medicinal cannabis products could also be manufactured and/or supplied for sale by

applying for a "Commercial Manufacturing License" ("CML") to the relevant Victorian Government agency or department(s) responsible for administering the scheme, which could be operated:

(i) as a stand alone manufacturing business model; or

(ii) as a manufacturing operation with a dispensary to supply medicinal cannabis products authorised under prescription to patients within the scheme; or

(iii) as a manufacturing operation with a cultivation license to produce cannabis to manufacture medicinal cannabis products; or

(iv) as a manufacturing operation with a cultivation license to produce cannabis to manufacture medicinal cannabis products, together with a dispensary to supply products authorised under prescription to patients within the scheme.

7.46 Compassionate Clubs / Co operatives could apply for appropriate licenses (including DPL (A)'s to the relevant Victorian Government agency or department(s) responsible for administering the scheme to operate:

(i) as a Compassionate Club with a dispensary; or

(ii) as a Compassionate Club with a Medicinal Cannabis Clinic and dispensary.

7.47 Recommendations for:

- license eligibility;
- requirements for License applications;
- conditions applying to the operation and renewal of licenses;
- quality assurance standards and risk management processes for:

    - patients, parents, guardians and carers
    - General Medical Practitioners
    - Medicinal Cannabis Practitioners
    - Medicinal Cannabis Dispensary Practitioners
    - Medicinal Cannabis Dispensaries
    - Medicinal Cannabis Clinics
    - Compassion Clubs/Co-Operatives
    - Cannabis Producers
    - Manufacturers of cannabis products.

- administering and regulating the scheme and how such could be used to further enhance the schemes operation and a play a role in scientific research and development of medicinal cannabis;

have also been address in this submission, as part of the medicinal cannabis scheme currently favoured for adoption in Victoria.

8. The immediate implementation and operation of an amnesty from legal prosecution for patients, parents, guardians, care providers and compassionate cultivators, cultivating, harvesting, supply, processing, manufacturing, using, supplying and selling cannabis for medicinal purposes.

PART SIX

COMMENTS ON FEATURES OF A PROPOSED MEDICINAL CANNABIS SYSTEM

COMMENTS ON FEATURES OF A PROPOSED MEDICINAL CANNABIS SYSTEM

A DEFENCE FOR MEDICINAL CANNABIS USE

1. It is acknowledged that a robust comprehensive regulatory scheme meeting the regulatory objectives referred to, is desirable. Providing a ''defence'' with or without an executive direction for Victorian Police to exercise a discretion in favour of medicinal cannabis patients, as a stand alone solution for medicinal cannabis use, is inadequate for the following reasons:

    a. A 'defence'' arises within the context of legal process and legal process requires an extensive investment of time and resources of a physical, emotional and financial nature, that terminally or chronically ill patients and /or their carer's do not have;

    b. the proposal for a medicinal cannabis scheme arose directly from community concerns surrounding the potential prosecution of medicinal cannabis patients and those involved in their compassionate care. Patients and their carers do not want involvement in the legal process system;

    c. providing a defence does not remove prosecution and involvement in legal process;

    d. the exercise of discretionary powers do not provide certainty or remove the threat and fear of prosecution involving the patient and/ or their carer's in the legal process system;

    e. fails to address the issue of supply of cannabis to meet the needs of patients;

    f. fails to address and or protect the interest of parties exclusively cultivating for and supplying medicinal cannabis patients;

    g. fails to meet and / or is inconsistent with a number of desired regulatory objectives for a medicinal cannabis scheme, previously referred to.

2. A complete ''defence'' to possession and use of cannabis for medicinal purposes, was made available to patients in New South Wales last year.[430] who qualified for entry onto a state register, permitting them possess/use up to 15 grams of cannabis for medicinal use. The defence accompanied by an executive direction to NSW law enforcement not to prosecuted such patients, did little to alleviate the concerns held by medicinal cannabis patients, that they would not find themselves involved in stressful legal proceedings. The protection did not extend to the patients compassionate medicinal cultivators and / or suppliers and law enforcement continued to destroy crops and prosecute such parties. Patients were left with increasing problems associated with supply.

3. The Victorian government could go beyond providing a simple defence and proceed to amend and or seek the amendment to relevant Victorian legislation authorising:

- the possession, use, and administration[431] of medicinal cannabis;
- the cultivation[432] of medicinal cannabis;
- the processing and or manufacturing[433] of cannabis;
- the supply and or sale[434] of medicinal cannabis;

for, by and or on behalf of natural persons.

and could rely on these amendments and proceed to issue licenses to formulate a Victorian medicinal cannabis scheme.

4. There are some present limitations[435] with the Victorian Government being able to do this successfully and without the co operation of the Commonwealth.

GOVERNMENT CONTROL OF SUPPLY OF MEDICINAL CANNABIS

1. The Netherland's government controls the operation of a medicinal cannabis scheme via a state authority referred to as the Office of Medicinal Cannabis, which is responsible for:

- licensing of cultivation;
- limiting the form permitted to be supplied (dry plant material only);
- supply;
- distribution (including- dispensing, import/export);
- quality control;
- product labelling; and
- price.

2. Bedrocan BV cultivates cannabis for the Office of Medicinal Cannabis under contract and is currently the sole licensed cultivator, supplying the Netherlands and some other countries with medicinal cannabis. It offers four strains of cannabis and one strain of CBD rich hemp. It subjects the plants to testing for: flower appearance, terpene profile, THC and CBD concentrations, as well as for the absence of contaminants, insects/mircro organisms, fungi, mould and heavy metals. The results of its laboratory testing are published online. THC: CBD percentages assist doctors with strain and dose selection.

3. It is acknowledged that cultivation controlled by the state offers the following benefits:

- control over quality;
- control over quantity;
- control over diversion to the illicit market; and
- less regulation and expense to the government in the operation of this scheme compared to alternatives.

4. This submission does not support this model for the following reasons:

   a. regulatory concerns and cost take precedence over the interests of patient's and their health;

   b. optimal therapeutic outcomes cannot be obtained with four strains of the cannabis plant to meet a wide variety of patient illnesses and individual

biochemical needs;

c. patient's are not restricted in their general access to other medications and should not be so restricted in their access to cannabinoid medicines;

d. it is not competitive enough with the illicit market. Limited choice will not meet patient needs. Health Canada who initially adopted a similar model and offered one strain of cannabis, found that patient's were not supporting their model for this reason and were returning to the illicit market; [436]

e. In the Netherlands, The Netherlands Department of Health Bureau of Medicinal Cannabis, estimated that there were 14,000 or more, medicinal cannabis users prior to the introduction of their medicinal cannabis scheme. Upon its introduction there were only 600 registered users. Ten years later, that number is approximately 1,200.[437] This suggests a high number of patient's are dissatisfied with the limited access to cannabis strains and the model as a whole. Similarly, in Canada of 38,000 licenses issued by Health Canada under its existing medicinal cannabis program, 28,000 of those licenses have been issued to individuals who have elected to forego the cannabis supplied by the Canadian Government in favour of growing their own cannabis;[438]

f. Laboratory testing of the nature referred to and electronic publication of results, is commonly offered in commercial models in other jurisdictions;

g. A lack of competition, results in a static price, loss of innovation and will stifle scientific research in Victoria and around Australia associated with cannabinoid therapeutics and horticultural practices associated with cannabis cultivation;

h. Will result in the loss of a lucrative cannabis industry for Victoria, and a loss of revenue for the state. The government regulatory model, as distinct from the government complete control of supply model, is highly successful and lucrative in Canada and the USA. In 2014 the cannabis industry in the USA grew by 75% producing $2.7 billion dollars in sales 20% wholesale and 80% retail sales.[439] Of the $1.2 billion dollars generated in retails sales, 82% of those sales, were generated by the medicinal cannabis market. US states last year, generated state sales revenues between, $200 to well in excess of $800 million dollars.[440] The US state of Colorado generated in the vicinity of $500 million from the sales of medicinal cannabis alone;[441]

i. It fails to meet a number of the stated Regulatory Objectives for a proposed scheme.

GOVERNMENT REGULATION OF SUPPLY OF MEDICINAL CANNABIS

1. A vertical supply and distribution model of the nature referred to previously at "Proposed Models for a Medicinal Cannabis Scheme: Government Regulatory Model" and regulated by:

    - a Victorian Government agency in the form of a statutory body; or
    - delegation of regulatory responsibilities spread across a combination of existing Victorian Government departments;

    is the model favoured by this submission.

2. It is envisaged that a Victorian Government agency or department(s) under a proposed medicinal cannabis scheme would attend to the following:

    - Maintaining an electronic database to assist in:

        - issuing, amending, renewing or revoking licenses;
        - prescribing medicinal cannabis;
        - housing and cross referencing data to oversee the general possession and supply of cannabis under the scheme, so as to prevent diversion to the illicit market,
        - regulating and improving the medicinal cannabis industry and assisting towards scientific development and research.

        The database would be accessible (in part) to the following participants under the scheme:

        - Patient's General Medical Practitioners and hospitals;
        - Patient Medicinal Cannabis Practitioners;
        - Medicinal Cannabis Dispensary Practitioners;
        - Law Enforcement Officers;

    - Registering, issuing, amending, renewing suspending and revoking licenses under the scheme for:

        - General Medical Practitioners;
        - Medicinal Cannabis Practitioners;
        - Medicinal Cannabis Dispensary Practitioners;
        - cultivation of medicinal cannabis;
        - Medicinal Cannabis Dispensaries;
        - patients, parents, guardians and carers holding licenses in the form of a Medicinal Cannabis Card;
        - Compassion Clubs;
        - manufactures of cannabis products and paraphernalia;

- Compliance: inspection and/ or auditing of:

    - cultivators: directly and or with the assistance of Local Municipal Councils;
    - manufacturers;
    - Medicinal Cannabis Dispensaries;
    - Compassion Clubs;

  either directly or in association with Local Municipal Councils;

- License suspension and or revocation**:** for non compliance with regulations i.e. submission of false documentation, sale to unauthorised third parties, failure to comply with license condition and general legislative requirements governing the parties and scheme;

- Enforcement: penalties and prosecutions for serious regulatory breaches and or non compliance;

- Dispute resolution/appeals process related to the issue, amendment, renewal, suspension or revocation of licences, license fees and penalties, failure to comply with regulations or license conditions;

- Revenue**:** overseeing revenue obtained from the scheme and allocating it towards providing services and education to support the schemes continued operation and improvement, together with scientific research associated with the medicinal use of cannabis;

- Education – providing educational modules for:

    - General Medical Practitioners to incorporate in their continuing medical education programs as a mandatory requirement associated to the renewal of their annual practising licence;

    - accreditation of Medicinal Cannabis Practitioners and their staff as well as the general public;

    - hospitals, hospices, nursing homes, retirement homes, schools, employers, real estate agents and the general public.

THE COST OF MEDICINAL CANNABIS

1 A patient must be able to access medicinal cannabis under any proposed scheme. Barriers, which stand in the way of access, must be identified and addressed so that patient's are not denied relief from pain and/or suffering.

2. The cost of medicinal cannabis can be a significant barrier to access.

3. Many chronically and terminally ill patients' suffer financial hardship. Cannabis pharmaceutical grade medicines, such as Sativex can be prohibitively expensive and out of reach to most patient's. Medicinal cannabis however, can be cultivated for as little as $0.38 a gram.[442]

4. The cost of cannabis provided by the Netherlands Department of Health Bureau is currently $5 Euro's or $8 AUD. The cost of cannabis supplied under Health Canada's medicinal cannabis scheme is $5-$12 per gram. In Israel, a month's supply of medicinal cannabis is capped at $100.[443]

5. The cost of obtaining medicinal cannabis is directly related to the quantity associated with a patient's daily dose of medicine required for symptom management and or to address an underlying medical condition.

6. There are few studies on the quantities of cannabis being used for medicinal purposes.

7. The average daily dose of medicinal cannabis in Canada has been documented by both Health Canada and large patient's studies to be between 18 and 28 grams a day, with some patients requiring doses up to 250 grams a day. [444]

8. The right of a patient to cultivate cannabis for medicinal purposes is currently before the Canadian Federal Court. Evidence tendered before the court in the matter of Allard –v-R,[445] suggests:

    a. a financially disadvantaged patient on a daily dose of 25 grams of medicinal cannabis is required to spend between $3,750 and $7,500 per month to receive cannabis medication supplied by Health Canada at a cost of $5 to $12 grams respectively;

    b. pensioners or the financially disadvantaged patient's under the Canadian scheme are unable to purchase cannabis in sufficient quantities to manage their symptoms at the rate of $5 per gram;

    c. such patient's are foregoing daily necessities in order to have access to very small quantities of medicine;

    d. many of these patient's are unable to purchase cannabis medicine at $5 per gram at all for periods of time;

    e. some patient's under the scheme had incurred interest bearing debts associated with Health Canada, in attempts to purchase at these prices with a number of patient's being unable to repay their debt;

f. cannabis can be produced under a Personal Production License for $0.38 to between $1-$2 per gram at cost; and

g. without the ability to produce under a Personal Production License, many patients are denied access to their medicine.

9. Under Health Canada's scheme, licensed commercial cultivators were not always in a position to grow for a patient and or be able to keep up with demand for particular strains of cannabis. There was also no regulation with regard to ''compassionate'' pricing by such licensed producers. Some offered compassionate pricing and some did not. [446]

10. There are many patients on disability support allowances, pensions and or limited incomes who are presently spending much of their current allowances on cannabis at street prices. These prices vary from under $10 per gram through to $60 per gram,[447] with The Global Drug Survey of 2015[448] founding that the price of street drugs such as cannabis in Australia, is more than double the global average. Consequently, these same patients can only medicate periodically because of the financial and relationship strains associated with the ability to access their medicine. The quality of their lives and personal relationships suffer greatly as a result. As previously discussed[449]some patient's finding this situation intolerable, are forced into illicit cultivation and other undesirable criminal activity to cover the costs associated with overcoming financial access barriers in order to obtain their medicine and live with some relief from their pain and continued suffering.

11. Financial barriers to access must be successfully addressed if patients are to have lawful and safe access to cannabis. The Canadian experience demonstrates that a failure to establish a compassionate price for cannabis, simply resulted in patient's supporting the illicit market where they obtained cannabis more cheaply and with the assistance of operations such as Compassion Clubs, that arose in part, as a response to this and other failures in the original Canadian medicinal cannabis scheme model.

12. This submission supports:

- the supply of cannabis by licensed producers and dispensaries, at compassionate prices and on a not for profit business model. This is in line with many jurisdictions currently operating programs in the USA [450] who have reported extraordinarily healthy revenues from such sales;

- the regulation of compassionate pricing and or other measures to facilitate the provision of cannabis medicine to the financially disadvantaged is mandatory;

- the provision of personal cultivation licenses and/or delegated production licenses;

- a mandatory requirement of commercial licensing that producers set aside a percentage of their total cultivation allowance, to grow a specific percentage of plants under nominee or designated growing licenses, for and on behalf of the financially disadvantaged, for a nominal fee;

- compassionate pricing should be adopted ideally being set ''at cost'' for the financially disadvantaged.

FORMS OF MEDICINAL CANNABIS

1. It is acknowledged that some overseas jurisdictions have placed restrictions on the forms of medicinal cannabis that are available to patient's within the operation of medicinal cannabis schemes.

2. Some schemes are now grappling with the consequences of these limitations. This is particularly evident in jurisdictions in the USA that passed CBD only medicinal cannabis schemes/products.[451] This was largely in response to witnessing the effectiveness of CBD as a medication in some children with some forms of epilepsy. However, low THC/ high CBD products have limited applications even for some of the children that initially benefited from their use. For example, some children with Darvet Syndrome, a severe form of epilepsy, have found that CBD only medications can make seizure activity much worse.[452]. Subsequent to passing ''CBD only legislation'' these jurisdictions discovered that whilst Low THC/high CBD my have worked for a very small percentage of patients[453], the same patients subsequently required high levels of THC or at least more THC than was permitted under their schemes. [454] CBD only products do not deliver the medicinal entourage effect associated with cannabinoid science One parent summarizes the situation well:

   "CBD is a very important part of the mix, but only part. We saw minor seizure control and developmental progress with CBD alone, but we didn't see real seizure control until we added measurable levels of THC to the mix."[455]

   "Others see great results with THCA added in. Some see very good results with no CBD, like in New Jersey, where there is little to no CBD available. The point is this is highly individualized medicine. There is no magic bullet."[456]

   A USA advocate and pediatric medicinal cannabis pioneer, Jason David[457] reported:

   "Many other parents in California tried Charlotte's Web (CBD only) and while a lot are having success, others are not getting seizure control with Charlotte's Web," says David. "They have different options in California to try different kinds of medical cannabis, and many have found that different strains and ratios are working to control their kids' seizures instead. Low THC/high CBD doesn't work for everyone; just like pharmaceutical medications, it's not one size fits all."

3. The CCV supports the science disclosing the entourage effect of cannabinoids and other components in the cannabis plant. This submission does not support, low THC/high CBD medicines or those that isolate one cannabinoid component and or promote it for general wide spread use and application. Cannabis medicine cannot be approached in this way. It must be specifically tailored for and to, a patient's individualized needs. Further, isolating cannabinoid medicines, such as low THC/high CBD and promoting them for general medicinal use ignores the needs of the many other patients who would benefit from THC. Scientists in Canada report[458] that the most frequent users of medicinal cannabis are in fact patients requiring pain management and that high CBD relative to THC brings about less pain relief. The majority of patients requiring cannabis medicine rely on THC. The work of the Marijuana Policy Project in the USA, supports this finding stating that ''the vast majority of [all medical marijuana] patients have symptoms that benefit from strains of marijuana that include more than trace amounts of THC."[459] This is due to the entourage effect, which is responsible for addressing a wide range of ailments including pain, inflammation, depression, anxiety, fungal and bacterial infections, immune regulation and cancer.

4. This submission does not support the idea of limiting forms of medicinal cannabis under the operation of a proposed medicinal cannabis scheme for Victoria. This submission has promoted the unique applications and circumstances in which various forms of cannabinoid medicines serve particular patient ailments and needs. A patient's ability to access cannabis medicine is a key requirement of any proposed scheme. That implies that the medicine must be appropriate and in the form appropriate for the patient. Access to cannabis medicine is an intrinsic human right.

5. This submission does believe that regulation is necessary to address advertising and the promotion of Industrial Hemp Oil products. Hemp Oil, although high in CBD has only traces of THC. As it is devoid of the entourage effect associated with more significant quantities of THC found in cannabis being used for medicinal purposes, it should be clearly distinguished from such via appropriate regulations regarding its general promotion and any claims made regarding medicinal or therapeutic use.

6. Medical concerns about the potential dangers of smoking cannabis have been demonstrated to be largely unfounded and any adverse effects are associated with the use of tobacco. Medicinal cannabis clinics in other jurisdictions advise against patient's using tobacco with cannabis.

7. Butane extraction and similar methods can be dangerous if performed by careless people, but are rare and expensive in Australia. Concerns regarding such methods can be addressed via appropriate licensing conditions and regulations.

8. Extractions and concentrates as cannabis medicines are very important because of their purity. Further, doses of cannabinoids are more uniform in these medicines, for which standardisation takes place during processing. There is no scientific botanical or pharmacological reason to distinguish between whole dried plant material and the resin produced from the glandular trichomes, that would justify access to one form of medicine but deny access to another. [460]The glandular trichomes are isolated from the plant, to obtain resin[461]. As such, the resin is considered to be less of a risk to health than risks associated with plant material, which may, (depending on how it is produced and processed) contain pesticide residue, heavy metals, mould, fungi and insects. Accordingly, it makes little or no sense to deny patient's access to concentrates and or extracts. Further, different extraction methods, provide access to specific cannabinoids (i.e. activation and cold water extractions can isolate CBC) that may be required in greater quantities to other cannabinoids, for greater therapeutic results. To deny patient's access to concentrates or extracts serves no valid medical purpose. The patient benefits from having a wide variety of forms and method of application and ingestion. For some conditions, certain forms are far more therapeutic than are others.[462]Edibles have been cited as such an example and are specifically made available for children in Israel[463]. The versatility of the medicine in its variety of forms, dosage and application, is the key to effective cannabis therapeutic outcomes. All of these products should be made available to patients just as a variety of pharmaceutical products are.

9. To restrict access to certain forms of cannabis medicine is not logical and has no scientific basis or merit. It would however, in effect, deny some patient's access to medicinal cannabis therapy.

10. To restrict access to certain forms of medicinal cannabis, would not be in accordance with the stated Regulatory Objectives of a proposed scheme

PART SEVEN

ACCESS TO MEDICINAL CANNABIS

ACCESS TO MEDICINAL CANNABIS

1. It is acknowledged that in defining what might constitute ‘’exceptional circumstances’’ that would permit a Victorian patient to have lawful access to cannabis under a proposed medicinal cannabis scheme, the Commission has referred to the need:

   - for an evidentiary medicine based approach;
   - to identify medical conditions from scientific medical literature for which cannabis has been demonstrated to be efficacious;
   - for benefits associated with medicinal cannabis not being reasonably available from other treatment options; and
   - for treatment to have a reasonable prospect of an advantageous outcome without an unacceptable downside.

EXCEPTIONAL CIRCUMSTANCES ACESS CRITERIA

1. The Commission states at **paragraph 3.1 of the issues paper** that to identify what might constitute ‘’exceptional circumstances”:

   a. it is ‘’first necessary’’ to consider scientific research findings about claims associated with the efficacy of cannabis; and

   b. evaluate that evidence so as to identify those Victorians most likely to benefit from its use in order to;

   assist in making a determination as to how the government could ‘’appropriately’’ and ‘’compassionately’’ delineate circumstances that would grant lawful access to cannabis for Victorian patients.

2. The evidentiary approach taken by the Commission to identify and define ‘’exceptional circumstances’’ focused upon:

   a. the efficacy of medicinal cannabis in scientific literature;

   b. a determination as to whether and to what degree, superior treatments may exist for certain conditions; and

   c. whether medicinal cannabis should be offered as an adjunct to other treatment options.

3. It is submitted that this approach is flawed because it operates on the basis of the following assumptions:

   a. that cannabis in all its forms would be a registered medicine for the purposes of the national therapeutic goods scheme;

   b. registered medicines are assessed for their efficacy and therefore cannabis must be assessed in this manner;

   c. registered medicines are assessed for the superiority over pre existing

medicines and or treatments.

4. It is submitted that these assumptions are incorrect and fail to recognize:

   a. cannabis is not primarily a ‘’therapeutic good’’ and or a ‘’medicine’’ for the purposes of the national therapeutic goods scheme;

   b. only registered “medicines” governed by the national therapeutic goods scheme must be shown to be efficacious and further;

   c. registered “medicines” governed by the national therapeutic goods regulatory framework are not required to demonstrate that they are superior to existing medicines; and so

   d. evidence as to:

      (i) whether other forms of treatment exist; and or
      (ii) the extent to which they may present as better treatment options; and or
      (iii) whether cannabis should be offered as a main or adjunct treatment;

   are not appropriate or material.

5. It is submitted that the approach taken by the Commission calls for a higher evidentiary threshold than is currently/and or should, be applied to cannabis. The Commission is referred to previous comments at ‘’Regulatory Framework for a Medicinal Cannabis Scheme” paragraph 2 (i)-(xix).

6. The Commission is referred to “Regulatory Objectives’’ and ‘’Comments on Regulatory Objectives and Terms of Reference’’ paragraph 3 to 8.

7. There is an increasingly large international patient population who over the past 25 years who have been successfully and safely provided with medicinal cannabis. This patient population continues to grow at a healthy rate. Given the role of medical practitioners roles in these jurisdictions as gatekeepers, together with the size of the international patient population being referred into medicinal cannabis programs, this should arguably be viewed, in and of itself, as sufficient evidence of efficacy and safe use. The existing body of scientific and historic evidence of safe and efficacious use of cannabis, should not be overlooked either. These matters further question the need for the Terms of Reference (to define ‘’exceptional circumstances’’) together with the current approach taken to define such through a legal lens, especially when balanced against the current demands and desires of the community for lawful access to medicinal cannabis on a compassionate basis, and the current degree of human suffering and loss of life in Victoria.

8. The UN Single Convention on Narcotic Drugs 1961 recognized in 1961 that cannabis was ‘’indispensible’’ for providing relief from pain and suffering. The term “’indispensible’’ implies the existence of an undeniable benefit associated with the its use. Once again, it questions the need for the Terms of Reference i.e. providing cannabis in’ “exceptional circumstances’’ and approaches to define it the manner attempted. The appropriate evidentiary evaluation to determine lawful access, which might have been: ‘’is a patient likely to obtain an efficacious benefit from using cannabis for their pain and / or suffering, in order to justify allowing a patient access to medicinal

cannabis?'' could, in view of the wording in the Convention, be reduced simply to: ''does the patient have a medical condition involving pain and / or suffering, which could be alleviated by medicinal cannabis and improve their quality of life?

9. It is submitted that where it can be shown that:

   a. a patient is likely to receive relief from pain and/ r suffering (as recognised by the UN Single Convention on Narcotic Drugs 1961) that would improve the patients quality of life; and

   b. the expected relief from pain, suffering and/or an improvement in the patients quality of life outweighs any perceived risk to that patient;

   then a patient should be given access to medicinal cannabis under a medicinal cannabis scheme. Further considerations as to efficacy are not required for reasons previously addressed.

   Such circumstances could be viewed as ''exceptional'' to the general rule of prohibition.

10. Attempts to define ''exceptional circumstances'' are unwarranted and are not, it is submitted, in line with the nature of:

   - the spirit and intent of the UN Convention;
   - a compassionate medicinal cannabis scheme; or
   - a number of Regulatory Objectives identified for designing a proposed medicinal cannabis scheme. [See: "Regulatory Objectives" and "Comments on Regulatory Objectives and Terms of Reference" in this submission.]

11. It is considered that should the Victorian Government insist on designing a medicinal cannabis scheme employing access criteria on the basis of ''exceptional circumstances'' that the health and life circumstances of a patient as outlined in paragraph 4 at "Comments on Regulatory Objectives and Terms of Reference"" should be used to define access.

12. Reference is made to **paragraph** 3.89 of the issues paper. Save and with the exception of pharmaceutical grade products such as Sativex et al, orthodox medical trials establishing safety and efficacy (required of regulated medicines under the therapeutic goods scheme), are not relevant to, and or required in respect to the use of the cannabis plant material and its products.

EVIDENCE BASED MEDICINE

1. This submission concurs with the statement made **in the issues paper at paragraph 3.90** that: ''a scheme that makes cannabis available in exceptional circumstances for persons with particular health needs should be driven by compassionate consideration which provides treatment options not wholly established by orthodox, double blind, placebo-controlled trials."

2. The Commission is referred to the safety and favorable toxicity profile of cannabis and remarks made in this submission at "Safe and Effective Use of Cannabis''.

3. Associate Professor Emeritus of Psychiatry at Harvard University, and internationally

acclaimed author and educator on medicinal cannabis, Lester Grinspoon states:

> ''There is no question about its safety. It is one of humanity's oldest medicines, used for thousands of years by millions of people with very little evidence of significant toxic effects. More is known about its adverse effects than about those of most prescription drugs. The American government has conducted a decades-long multimillion-dollar research program in a futile attempt to demonstrate toxic effects that would justify the prohibition of cannabis as a non-medical drug. Should time and resources be wasted to demonstrate for the FDA what is already so obvious?"[464]

4. This submission does not support the call for further clinical trials where such trials would result in a delay in introducing a medicinal cannabis scheme and / or where such might be used to determine or further refine, who might have lawful access to cannabis under a proposed medicinal cannabis scheme. It is considered that such an approach is detrimental to the health and wellbeing of Victorians currently using and or desiring to use medicinal cannabis. The continued failures on the part of the Commonwealth and Victorian Government to carry out the obligation under the UN Single Convention on Narcotic Drugs 1961 to make adequate provision for the availability of cannabis for medicinal purposes, is a continuing breach of the Human Rights of all Victorians.

5. Notions of a reasonable expectation of therapeutic benefit associated with medicinal cannabis use are customarily tethered to calls for further clinical trials. However, pharmacological products are available on the basis of few and in some instances, a sole clinical trial[465] and many are approved notwithstanding contradictory clinical trial findings[466]. The Commission is referred to paragraph 13 in the "Safe and Effective Use of Cannabis,'' in this submission.

6. A balance must be attained between the channeling of resources (the financial expense to the community associated with clinical trials), the need for certainty, safety and efficacy (for registered medicines) and the moral duty to provide relief for human suffering when regulatory systems are not addressing societal needs.

7. There is a large body of scientific literature on medicinal cannabis involving favorable robust clinical trials, pre clinical studies, in vivo laboratory studies, in vitro animal studies, case reports and clinical observations. Collectively, they are all recognized as a part of the scientific process and individually, should not be dismissed.

   Case reports and clinical observations form the initial basis for medical sciences knowledge, highlighting promising applications for plant derivatives and synthetic medicines.[467] Such knowledge informs and drives proposals for clinical trials.

   Controlled experiments are not always required in order to meet FDA/TGA approvals. Controlled experiments were not required for: chloral hydrate, barbiturates, aspirin, curare, or lithium.[468]

   Clinical observation has resulted in many ''off label'' uses that have resulted in their subsequent regulated approved uses. Examples of such drugs include: propranolol for hypertension, diazepam for status epilepticus and imipramine for childhood enuresis.

   In 1976, several small and imperfect studies observed the role of aspirin in preventing a heart attack. These studies were followed up in a large study 12 years later, which

demonstrated the efficacy of aspirin so dramatically, that the trial was immediately stopped so that the life saving benefits of aspirin could be given to those at risk of adverse cardiac events. [469]Cannabis has been said to be like aspirin: a substance that is known to be unusually safe, delivering enormous benefits[470]. Whilst a study was required to demonstrate the long term effects of aspirin, there are innumerable case reports of cannabis bringing instant relief from symptoms, which can be measured, in a single person. Such case studies are referred to as N-of-1 clinical trial, or the single patient randomized trial. These are recognised scientific studies and they are numerous and widespread in many overseas jurisdictions.

8. Reference is made to **paragraph 3.91 of the issues paper**. Evidence based medicine is not without fault. On this point the Commission is referred to the work of Peter C Gotzsche, founder of the Cochrane Center and in particular his most recent publication ''Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Healthcare''. [471]

9. Departure from entirely evidence based medicine where benefits out weigh known risks has been a common approach in medical science where a societal need has been identified. A good example is antibiotic therapy, where empirical medicine is practiced. Treatment is administered on the basis of clinical observation before a diagnosis is confirmed. It is recognized that a departure from evidence based medicine is required in order to administer a life saving medication. Cannabis is a life saving medicine and this is no more clearly demonstrated in pediatric epilepsy.

10. The regulatory supply of vaccines needed to address pressing public health issues, is another example of medicines departure from standards generally employed with evidence based medicine. Where the public health demand is high, vaccines have been made available foregoing higher evidentiary standards and or trials of their use, which are usually employed in the regulatory processes.

11. There are precedents in support of the departure from evidence based medicine which are viewed as acceptable when medical science and regulatory processes are failing to meet the needs of society and society demands a departure from these standards to assist people who are suffering and dying. The precedents exist to support making medicinal cannabis available to Victorian patients now, without further delay.

12. It is questionable whether a reasonable therapeutic benefit needs to be evident simply because it might, as the Commission contends, otherwise ''raise false hopes''. If patients are permitted to enter into clinical trials of a novel therapeutic under such circumstances, then such an argument seems hollow and should not deny patient's access to medicinal cannabis on such a basis. Sometimes, hope is the only thing that keeps these patient's alive. The mind's role in healing, as demonstrated via the ''placebo effect'' in evidence based medicine, is powerful.

BENEFITS FROM OTHER TREATMENTS

1. This submission strongly opposes the contention of the Commission at **paragraph 3.91 of the issues paper** that any potential benefit associated with medicinal cannabis must be one that cannot already be reasonably obtained from another available form of treatment for the following reasons:

   a. a patient may be unable or unwilling to take many medications and or treatments, for

a variety of reasons including:

- pre existing conditions and general contra indications;
- chemical sensitivities;
- an inability to metabolize or tolerate certain drugs;
- adverse drug reactions;
- a desire to avoid stated risks associated with the treatments;
- the side effect profile of the treatment is unacceptable;
- an inability to access the treatment due to geography, regulatory or financial obstacles; and or
- a refusal to undergo treatments due to personal, religious or considerations of conscience.

b. such a stipulation is not a prerequisite to accessing other standard treatments and /or pharmaceuticals and to impose such in relation to the access of medicinal cannabis is unreasonable and unjust and implies a discriminatory attitude towards cannabis use;

c. Victorian patient's should not be denied lawful access to medicinal cannabis simply because they have chosen, for good reason, to forego an existing treatment;

d. It is highly questionable for the Victorian Government to force a patient in this manner, into an unsuitable treatment option that they might otherwise reject, in order to gain access to a more beneficial or suitable option, in the form of medicinal cannabis;

e. this requirement may deny and / or nullify a patient's right to health care and the consent that they might otherwise be free to provide. As such it raises a question as to whether and the extent to which this approach might encroach upon individual human rights under relevant state, federal and International Human Rights laws;

f. this requirement is not consistent with the Regulatory Objectives for a medicinal cannabis scheme.

ADVANTAGEOUS OUTCOME WITHOUT UNACCEPTABLE DOWNSIDE

1. This submission rejects the contention advanced by the Commission at **paragraph 3.92 of the issues paper.**

2. Reference is made to paragraph 7 "Exceptional Circumstances" above and once again makes reference to the large number of international patient's over the last 25 years that have been prescribed medicinal cannabis, and who's numbers are growing at unprecedented rates. It is safe to conclude from such, that clinical knowledge supports an advantageous outcome without an unacceptable downside.

3. If a patient including the terminally ill, can consent to and enter into clinical trials (especially those for a novel therapeutic agent), ''where clinical knowledge is not sufficient to hold out a reasonable prospect of an advantageous outcome, without an unacceptable downside" then it is hard to see why and how the justification can be maintained outside of that context and applied to medicinal cannabis therapy.

4. A patient (as demonstrated by subjects entering into clinical trials) retains the right to make an informed choice and decision with regard to what they perceive as an ''unacceptable down side''. Patient's should be given this choice, especially terminally ill patient's and / or patient's with rare diseases with no and or limited treatment options, and or patient's who for other reasons have no other suitable or effective treatment options available to them. These patients should not be denied this right.

5. This submission rejects the contentions advanced by the Commission at **paragraph 3.93, 3.94** and **3.95 of the issues paper**. The Commission is referred to remarks made in "Safe and Effective Use of Cannabis'' as a part of this submission and paragraph 2 above. It is uncertain who will sustain side effects from any new medications, what ever their nature and how severe and prolonged they might be. These factors are all unknown until the patient trials the medication. It is unknown whether and to what extent a patient may suffer from the conditions described and attributed to cannabis by the Commission at the paragraph referred to in the issue paper. Once again, these are matters for the informed consent and choice of a patient and or his or her guardian in the case of a child.

6. This suggestion is not consistent with the Regulatory Objectives for a medicinal cannabis scheme.

7. Reference is made to the Commissions remarks at **paragraph 3.96 of the issues paper.** The Commission is once again referred to the remarks made at paragraphs 6 to 8 in ""Access: Exceptional Circumstances".

8. With regard to the Commissions remarks at **paragraph 3.96 of the issue paper**, the following question must be posed: Why? Why shouldn't a compassionate scheme permit *all* ''sufferers'' of the ''numerous medical conditions'', that cannabis has been shown to be ''efficacious'' for access to medicinal cannabis? After all, ''efficacy'' of cannabis, has been suggested by the Commission as the evidentiary tool that may be most appropriate to determine lawful access to cannabis under ''exceptional circumstances".

9. The United Nations Single Convention on Narcotic Drugs 1961 recognizes that cannabis must be made available to alleviate pain and suffering. There is no further limitation or attempt to define access for lawful medicinal use. It is submitted that:

    a. qualifying access to cannabis on the basis of ''exceptional circumstances'' narrows access in a way that was not intended by the Convention;

    b. to add a further stipulation that not all suffers of all medical conditions for whom cannabis might be found ''efficacious'' and who might therefor be viewed as qualifying for lawful access (i.e. "under exceptional circumstances") will not automatically do so, further narrows the access funnel;

    c. to require such a stipulation is likely to lead to uncertainty as to the operation of the criteria; and

    d. the statement appears at odds with the Commission's previous statement at **paragraph 3.88 of the issues paper** and is inconsistent with the Regulatory Objectives proposed for a medicinal cannabis scheme.

ACCESS VIA LIST OF SYMPTOMS & MEDICAL CONDITIONS

1. A number of jurisdictions noted by the Commission have formulated a lawful access criteria associated with cannabis for medicinal use, on the basis of one or more of the following:

    a. a list of symptoms;
    b. a list of medical conditions;
    c. a hybrid model including a list of symptoms and conditions;
    d. a hybrid model together with a general ''catch all'' provision to cover additional circumstances;
    e. leaving the decision to a General Medical Practitioners discretion;
    f. leaving the decision to a General Medical Practitioners discretion with one or more of the above criteria to be used as a guideline.

2. Lists, whether of symptoms or conditions:

    - are generally exclusionary rather than inclusionary;
    - are contrary to the notions of a compassionate scheme;
    - are limited in their ability to alleviate suffering and exclude many people in need;
    - are aptly referred to as ''Schindler's Lists'' creating a perception of the deserving and the undeserving ill; and
    - are inconsistent with compassion and the Regulatory Objectives of a medicinal cannabis scheme.

3. A list whether of symptoms or conditions may or may not provide certainty and confidence to time poor or ignorant medical practitioners who may be unable or reluctant to consult scientific literature on the therapeutic benefits of cannabis. This barrier may be overcome by compelling such practitioners to undergo cannabis education as a part of the mandatory continuing medical education program associated with the annual renewal of their professional licensing requirements and subsidized out of the revenues raised by any regulatory medicinal cannabis scheme. Many individuals within the CCV believe that this will be necessary irrespective of the adoption of eligibility criteria that may be set down in the form of a list. A scheme is of little use, unless a patient can be given access to medicinal cannabis and those involved in making such a determination must be educated to preclude their otherwise reluctant participation.

4. A list of symptoms will not provide certainty to even the most educated medical practitioner on whether to prescribe or recommend cannabis to a patient who's symptoms do not quite fit the description provided or who's symptoms, which may be the result of a chronic condition are not active at the time of the request.

5. Some jurisdictions have made a list of symptoms as a category separate from, but in addition to, a list of medical conditions.

6. However, depending on how such is drafted, it could be read in a manner that is unnecessarily restrictive. i.e. symptoms relating to and stemming directly from the listed conditions.

7. The problems of this approach can be found in the following example. Idiopathic CD4 lymphocytopenia, is a very rare condition where a patient has an inexplicable loss of a group of white blood cells or specifically T cells (CD4). The condition is also referred to as Non HIV+ AIDS. That is to say, that the patient has AIDS but has no evidence of and / or does not have the HIV virus. A patient with this condition may have symptoms on a symptom list that might qualify them for access to medicinal cannabis. However, if the symptoms are to be read as being due to the medical condition HIV/AIDS, that patient may not qualify for lawful access to medicinal cannabis, as the patient does not have AIDS caused by the HIV virus.

8. A list of symptoms to be read as relating to and or stemming from the listed conditions might also require a referral to one or more specialist physicians to certify that the symptoms relate to and or stem from, the medical condition. This is an expensive and time-consuming process. It is not uncommon for patients to have to wait for up to 8 weeks or more, to see a specialist physician. Terminal and chronically ill patients with intolerable suffering do not have the luxury of time to invest in such a process. Physician's fees can range from $270 up to $700 for a consultation. For the many patient's who survive on disability support allowances, they will be unable to access such services and in turn, will not be able to access medicinal cannabis. Medicinal cannabis must be accessible to those who need it and it must be accessible in a timely and cost effective manner.

9. Health Canada under its initial proposed medicinal cannabis scheme adopted a list of symptoms, which was to be read in association with specific medical conditions. Unsurprisingly, this aspect of the Canadian medicinal cannabis system was not embraced by the patient's [472]who reported great difficulties in being able to access the scheme for the reasons referred to above. It was far easier and much more economically viable for Canadian patients to return to the illicit market, which they did. As a result, the Canadian Government subsequently abandoned this stipulation, replacing it with the requirement that the medical determination be made by patients General Medical Practitioner on the based on the exercise of their professional judgment and discretion. Health Canada also published reference materials to assist Canadian medical practitioners in their decision making process. Victoria would be wise to learn from this experience and avoid repeating this error.

10. A list of symptoms to be read subject to specific medical conditions is inconsistent with the Regulatory Objectives for a medicinal cannabis system.

11. Lists do not keep abreast with medical scientific developments and will therefore exclude access for many patients in need. A PubMed search, undertaken by NORML [473] in the USA, found of the 20,000 plus pieces of scientific literature on cannabis and its medicinal applications, over half of these publications were made in the last 5 years alone. This provides some indication of how rapidly science is progressing in this field and how quickly a fixed list of medical symptoms and or conditions would become dated. It should be kept in mind, that the current proposal for a medicinal cannabis scheme in ''exceptional circumstances'' has arisen precisely because of and as a direct response to, the inability of the current medical, scientific

and regulatory systems to keep up with developments in this area and or meet societal needs. It would therefore be a self defeating waste of tax payers money in designing a regulatory system intended to address these matters, to subsequently adopt a design feature that would only produce the same or similar outcomes.

12. In recognition of this fact some jurisdictions have provided a means to have the lists amended from time to time, involving an administrative appeal's type process. However, such this mechanism fails to acknowledge that patient's do not have the physical, emotional or financial resources to invest in such a process. Further, the terminally ill and those experiencing intolerable suffering do not have the luxury of time generally required when participating in such processes. This makes for an unnecessarily cruel requirement. Faced with such hurdles, patients are more likely to return to the illicit market. Perhaps this is why some overseas jurisdictions that adopted this mechanism have not seen any modifications to their lawful access lists, since the inception of their schemes[474]. This option defeats and undermines the operations of any medicinal cannabis scheme and is inconsistent with the Regulatory Objectives stated for such a scheme.

13. A hybrid model of a list of symptoms or medical conditions and a general catchall criteria, is more equitable. The most comprehensive hybrid criteria appear to be that recently proposed by Alabama, USA, under bill 326.[475] The Alabama model lists 25 medical conditions and provides access to medicinal cannabis for any additional chronic or persistent medical condition not listed, which either '' (i) substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans with Disabilities Act (ii) have symptoms that could cause serious harm to the patient's safety or physical or mental health if not alleviated."

    Although comprehensive, it may still effectively have the end result of requiring a referral to a specialist physician on more than one occasion, to determine whether an unlisted condition ''substantially limits'' a patient's ability to conduct one or more activities defined under the Americans with Disability Act. In this regard it suffers from the same problems addressed at paragraphs 7 and 8 above. Further, the term "substantially limits'' is unnecessarily high, as it would deny persons suffering with a disability (to the extent that it was interfering with their day to day functioning and quality of life), access to a potentially beneficial therapeutic.

14. Whilst the type of list proposed by Alabama, USA is comparatively comprehensive, this submission does not support exclusionary and or limited access criteria's of the nature discussed. Further, this submission does not support models that have proved to be unsuccessful and have ignored and sacrificed the health requirements of patient's in favor of regulation and concerns associated with diversion into recreational markets. It is important that Victoria learns from and avoids mistakes made in other jurisdictions.

15. For these reasons, this submission supports a patient's General Medical Practitioner using his or her professional discretion to determine whether a patient should have access to medicinal cannabis. This approach has been successfully employed in the Netherlands, Canada and Israel.

16. This submission rejects proposals similar to those currently advocated in NSW to limit access to medicinal cannabis to patients with cancer, epilepsy and terminal conditions. It must be emphasized, that the idea of a medicinal cannabis scheme arose from members of the community for whom the current medical research, regulatory and

community system is failing. Such persons are not limited to those suffering from cancer, epilepsy or terminal conditions. It should also be noted, that the vast majority of medical research funds and associated resources in this country, are dedicated to and directed towards, cancer treatment and services. The current proposal for a medicinal cannabis scheme should recognize this factor and the medical orphans that such inequality (in terms of societies resource distribution), leaves behind. As for such jurisdictions calls for further medical trials to determine whether a medicinal cannabis scheme should proceed, this appears to be an extremely wasteful deployment of community resources, given the extensive existing historical medical and scientific evidence in favour of medicinal cannabis and its general employment in a large number of overseas jurisdictions.

17. Lawful access to medicinal cannabis as a compassionate redress to limitations in the existing scientific medical and regulatory model, must under any proposed system, be designed to ensure that as many people in legitimate need of medicinal cannabis are given access to it to address their pain and / or suffering and improve their quality of life. This is not only compassionate, but also consistent with the general communities expectations and desires, reflected and embedded in the United Nations Single Convention on Narcotic Drugs, as long ago as1961requiring that adequate provision must be made for such purposes.

AUTHORISING & PRESCRIBING MEDICINAL CANNABIS

AUTHORISING & PRESCRIBING MEDICINAL CANNABIS

It is acknowledged and / or submitted that:

1. authorisation to commence medicinal cannabis therapy would be required under a proposed medicinal cannabis scheme;

2. medical practitioners would play an instrumental role in any medicinal cannabis scheme in assessing the health of a patient and making a determination as to whether the patient:

    a) falls within a specified regulatory criteria; and / or
    b) recommended access based on their own professional discretion.

3. this submission favours the use of a doctors discretion. The Commission is referred to previous comments made at ''Access: Exceptional Circumstances'' in this submission;

4. effective participation of medical practitioners, as well as the extent to which they will do so, will be a crucial determinant of the success of any scheme;

5. those responsible for prescribing cannabis and caring for patients under a proposed scheme, should not be limited to medical practitioners but should also include herbalists, naturopaths and other allied health care professionals;

6. medical practitioners in Australia have openly expressed their reticence at involvement in a medicinal cannabis scheme. This is primarily due to concerns about having to deal with an unregulated herbal product and having to determine dosage, purportedly without any guidance or reference associated to dosing based on clinical trial evidence. Although medical practitioners titrate doses of a patient's medication, they only do so after starting from the position of a recommended dose, which has the endorsement of clinical trials. They are not accustomed to attempting to work out what dose may work for a patient using botanical substances and attempting to determine dosage by starting from a position of titration. It is however, the manner in which herbalist and naturopaths deliver therapeutic products and services to their patient;

7. the medical profession are unaware of and unfamiliar with, the existence and operation of the human endocannabinoid system and its significance. Herbalists and naturopaths are more engaged, interested and informed on cannabis as a herbal therapeutic and the subject matter in general. Allowing such practitioners to treat and prescribe under a proposed medicinal cannabis scheme would result in greater access to cannabis for patients in need. General medical practitioners' will therefore require education on the nature of the endocannabinoid system, medicinal cannabis and prescribing. This will be vital to instilling confidence in them to prescribe and participate in a medicinal cannabis system. This submission supports mandatory educational units on these subjects as well as on the regulatory operation of a medicinal cannabis scheme, which should be a part of the practitioners' continuing medical education and be undertaken as a condition of renewal of their professional medical licences;

8. medical practitioners are also time poor. They are stretched by large patient numbers, which they see in short consultations. The nature and structure of the present health care system does not cater for the type of medical consultation that a medicinal cannabis patient would need and required to ensure that:

- a patient was prescribed with an appropriate therapeutic cannabinoid medicine or mixture thereof;

- dosage is accurately assessed and determined using grams of weight/quantities of plant material and converting the same to mgs of THC per gram of plant matter or ml's per decilitre of oil or tincture when and where required without making errors that could leave a patient without sufficient medication;

- the appropriate forms and applications of medicinal cannabis are matched to the patient's circumstance;

- the patient is instructed in the proper and safe use and application of the various forms of medicinal cannabis;

- the patient is instructed in the proper and safe use of the apparatus used in the administration of medicinal cannabis.

9. some of the instructional matters referred to could be addressed by a time poor medical practitioner referring the patient to a registered allied health care professional operating under a scheme at a Medicinal Cannabis Clinic. Such constraints are not present for herbalists and naturopaths who are accustomed to longer and more relaxed consultations and who are knowledgeable and interested in herbal medicines, their formulation, applications and dosage which are customarily approached by titration;

10. the Commission notes at **paragraph 7.57 of the issues paper** that some matters could be regulated via the standards of the professional colleges within the medical profession. However, it would not address the practical realities of clinical practice associated with medicinal cannabis referred to above. Further, the danger of such matters being left to professional colleges who may well set standards and or recommendations that actively discourage participation by their members, must be considered. It is noted that this took place in some Canadian provinces under the operation of the Canadian medicinal cannabis program resulting in patients being effectively denied access to medicinal cannabis having to return to the illicit market. [476]It is vital that important stakeholders such as the medical profession, have their needs acknowledged and balanced with the corresponding needs of patients within the design framework of a proposed scheme. This is necessary if the medical profession is to embrace and participate in it's final form;

11. given these matters, the extent of the role of medical practitioners in standard clinical practices, the degree of their participation within any proposed scheme must be carefully considered. Access for patients to any proposes scheme must be a prime consideration under any proposed scheme. Given the problems associated with General Medical Practitioner participation additional practitioners [''Medicinal Cannabis Practitioners''] should be incorporated into a proposed scheme and given certification and prescribing rights. This would promote access to medicinal cannabis overcoming similar difficulties experienced in other jurisdictions;

12. this submission favours the following proposals.

13. the role of medical practitioners in a proposed scheme should be to:
    a. review the patient's medical history;
    b. provide the patient with a complete medical examination;
    c. certify that the doctor has attended to (a) and (b);
    d. certify that the a patient has a medical condition or symptoms involving pain and or suffering which could be assisted by prescribing cannabis;
    e. certify that the patient is eligible to be treated with medicinal cannabis;
    f. lodge electronically a statement containing the above material with the Victorian Government operated electronic database kept for such purposes and provides a copy to the patient and or patient's carer for their records;
    g. create a medicinal cannabis treatment plan for a patient stipulating amongst other matters, the Maximum Total Daily Dose of medicinal cannabis and/or the Total Daily Dose (where a patient is titrating dose up to the Maximum Total Daily Dose), lodging details of these particulars in the electronic data base operated by the Victorian Government for the purposes of the scheme;
    h. prescribe and treat patients using medicinal cannabis; or
    i. would attend to the matters at (a) to (b) and provide a letter to this effect to be provided to the relevant Victorian Government agency or department administering the scheme and/or for presentation to a Medicinal Cannabis Practitioner who would attend to the certification for the patient and include a statement in in that process to the effect that the matters at (a) and (b) had been attend to by a General Medical Practitioner and would thereafter proceed to treat the patient under a medicinal cannabis scheme. A medical practitioner would in such an instance, schedule a consultation to review the patient's progress after commencing medicinal cannabis therapy;

14. the certification and /or letter referred to at paragraph 12 (h), together with details of the patients Maximum Total Daily Dose could be lodged with the Victorian Government as part of the medicinal cannabis scheme and entered into an electronic database. A copy could also be provided to the patient, parent, guardian and/or their care provider;

15. a General Medical Practitioner (and or a registered Medicinal Cannabis Practitioner), to be able to access and complete the certification and any other necessary documentation required by logging into the electronic database operated by the Victorian Government using their professional registration identification numbers issued by the Australian Health Professionals Regulatory Authority (AHPRA) and or any registration number provided to them for the purposes of the scheme. This requirement would avoid any delays that might otherwise be caused by a failure on the part of such practitioners to lodge the certifications with the Victorian Government. It is important hat the patient's access to medicinal cannabis is not delayed.;

16. a General Medical Practitioner electing to treat and prescribe medicinal cannabis to a patient could under a medicinal cannabis scheme:

    a. determine the validity of a certification and Medicinal Cannabis Card;

    b. determine the validity of a certification for the purpose of the scheme. A valid certification might be one where:

        (i) the certification had been lodged with the relevant Victorian Government agency or department; and/or

        (ii) evidence of activation of a treatment plan in the form of medicinal cannabis having been prescribed and used by the patient within 12 months from the date of the certification;[477]. and/or

        (iii) the issue of a PPL or DPL (A) within the same time frame

    c. This would serve as a review mechanism to ensure the continued existence of a medicinal condition and need for medicinal cannabis therapy, where a patient had not acted promptly;

    d. Where the certification was not valid in the manner described a new certification would be required before treating and or prescribing medicinal cannabis for the patient;

    e. determine if the patient, parent, guardian or carer is registered in the electronic data base and holds a valid APL or Medicinal Cannabis Card. Where such a party is not registered in the data base or holds a valid Medicinal Cannabis Card from another jurisdiction the medical practitioner could be required to seek prior approval to treat and or prescribe from the relevant Victorian Government agency or department established for the purposes of the scheme;[478]

    f. proceed to treat and prescribe medicinal cannabis for a patient holding a valid Medicinal Cannabis Card with appropriate licenses;

17. a General Medical Practitioners would in addition to the aforementioned set out a medicinal cannabis treatment plant. This plan could include:

    - duration of the treatment plan up to 12 months;
    - commencement date of the treatment plan;
    - scheduled review dates under the treatment plan;
    - a patients commencing Maximum Total Daily Dose of cannabis medication ("MTDD");
    - a patients Total Daily Dose (where dose is being titrated slowly up to the MTDD;)
    - forms of cannabis;
    - recommended cannabis strains;
    - dosage instructions;
    - provide patient information sheet; [See: Annexure 1);
    - instructions on how to deal with unwanted side effects (if any).

18. a General Medical Practitioner or Medicinal Cannabis Practitioner would access the electronic data base in the manner previously described and complete a relevant form stating the duration of the patients treatment plan, the patients Maximum Total Daily Dose thereunder. This information would be used to assess and assist the relevant Victorian Government agency or department in the issue and regulation of Medicinal Cannabis Cards and licenses under the scheme;

19. alternatively, where a General Medical Practitioner does not wish to certify and or prescribe medicinal cannabis, they could either:

    a) attend to completing the certification for the purposes of determining lawful access under the scheme and allow the patient to seek treatment from a registered Medicinal Cannabis Practitioner; or

    b) where the medical practitioner did not wish to issue a certification, they could provide a letter to the patient for use of a registered Medicinal Cannabis Practitioner stating:

        - the doctor had reviewed the patients medical history;
        - the doctor had reviewed the patients medical condition and or symptoms;
        - that the doctor has performed a complete medical examination; and
        - any relevant considerations arising out of that medical examination.

    After confirming the content of the letter with a patient's General Medical Practitioner, a Medicinal Cannabis Practitioner could proceed to attend to the certification process referred to above.

20. the following health care professionals might be considered as appropriate for the role of Medicinal Cannabis Practitioners, for the purposes of a proposed scheme:

    - General Medical Practitioner;
    - Pharmacists;
    - Chiropractor;
    - Dentist;
    - Registered nurse;
    - Herbalist; / or
    - Naturopath.

21. these practitioners could be registered and licensed with the relevant Victorian Government agency or department for the purposes of a scheme, and issued with a practitioner registration code that could be linked to their professional AHPRA license registration number. All practitioners could be given treatment and prescribing rights for the purposes of a medicinal cannabis scheme by amending the Drug Poisons and Controlled Substances Act 1981 (Vic) and any other relevant legislation;

22. such practitioners should also be given the ability to certify whether a patient could be given access to medicinal cannabis for the purposes of the scheme. This would ensure that those patient's who's General Medical Practitioners were reluctant to do so, would

not be denied access to medicine. In circumstances where a patients General Medical Practitioner did not wish to issue a certification, the Medicinal Cannabis Practitioner using the letter provided by a patients general practitioner confirming:

a. the doctor had reviewed the patients medical history;

b. the patients medical condition and or symptoms;

c. that the doctor has performed a complete medical examination

noting any relevant considerations arising out of that medical examination could attend to determining whether:

(i) the patient has a medical condition or symptoms involving pain and or suffering which could be assisted by prescribing cannabis; and

(ii) certify that the patient is eligible to lawfully access cannabis under the scheme.

23. both General Medical Practitioners and Medicinal Cannabis Practitioners could be assisted in this determination by being provided with materials similar to those offered to medical practitioners by Health Canada under the operation of its medicinal cannabis program. Such practitioners to also under undergo appropriate medicinal cannabis education and or accreditation as the scheme progresses. Such could be provided by the Victorian Government as a part of the operation of the scheme;

24. Over time, the list of Medicinal Cannabis Practitioners could be expanded to include other allied health care professionals who might also receive registration as a Medicinal Cannabis Practitioner on the completion of an appropriate medicinal cannabis accreditation program. Until such a course is operational, it is considered that the professionals identified would be more than competent to execute the responsibilities required under the scheme, in the interim period;

25. as acknowledged by the Commission in the issues paper, in Vermont USA, naturopaths, physician's assistants and registered nurses are permitted to certify or determine whether a patient qualifies for access to their medicinal cannabis scheme. Similarly, Canadian nurses are also permitted to do so where they have prescribing rights;

26. Medicinal Cannabis Practitioners might choose to operate within a traditional medical practice, as a part of a Compassion Club/Co-operative or in a special Medicinal Cannabis Clinic with a dispensary similar to those operating in Canada and the USA. There are 103 compassionate health care clinics/dispensaries successfully operating in Canada today[479]. These health clinics run practices, which emulate their medical counterparts and offer a range of complementary therapies services and products. The clinics in Canada are not part of the regulatory medicinal cannabis scheme, but operate alongside it as a result of a number of successful law suites where Canadian courts acknowledged the human rights of Canadian patient's and the need and vital role such clinic's play within the community. These clinics/dispensaries are professionally certified/accredited by operations such as the Canadian Association of Medicinal Cannabis Dispensaries. Many in the USA, also undertake and or employ consultants to

provide guidance on risk management and regulatory compliance accreditation and educational training services. There are many individuals within the CCV who support this feature of a proposed medicinal cannabis scheme and would like to see similar accredited professional clinics operating in Victoria; [See: "Processing and Distribution: Medicinal Cannabis Clinic's" in this submission.]

27. whilst General Medical Practitioners act as ''gate keepers'' for a number of controlled and highly regulated substances, so do a number of the professionals identified as possible Medicinal Cannabis Practitioners for the purposes of this submission. Such parties in their respective fields also currently advise and help their patient's to: assess their health care options; their associated benefits and risks, as well as determining dosage and monitoring responses. These existing professional skills and duties could be directly transferred across and into the operation of a medicinal cannabis scheme;

28. where either a General Medical Practitioner or Medicinal Cannabis Practitioner elects to treat the patient, they would prescribe a Maximum Total Daily Dose of cannabis. An amendment to the Drugs Poisons and Controlled Substances Act 1981 (Vic) may enable such practitioners to attend to this;

29. each prescription[480] issued should set out:

    a. the patient's Maximum Total Daily Dose (''MTDD'') or Total Daily Dose where a patient is slowly titrating up to the MTDD, in grams of cannabis flowers and or mcg's of THC, CBD;
    b. each specific measure of cannabinoid as a ratio to other cannabinoids;
    c. terpene requirements or restrictions (i.e. No Myrcene to avoid drowsiness);
    d. product and form (i.e. flowers, concentrates, extracts, tinctures, edibles);
    e. methods of administration;
    f. direction as to when to take the specific cannabinoid (i.e. 3mg of Indica flowers 1 hour before bed; 3mg of Sativa flowers 3 x per day or 8 hr. intervals);
    g. directions for use and dosage schedule for each cannabinoid which is required to be taken separately (i.e. the period of time between doses for the different cannabinoids);
    h. where more than one form of cannabis is recommended whether prior cannabis medicines are to be maintained, reduced or discontinued;
    i. where more than one form of cannabis is to be taken- separate prescription for each form of cannabis to be taken by the patient should be issued.

Total medicine to be dispensed under a prescription or prescriptions would equate to a patient's specified percentage of their Maximum Total Daily Dose over the duration f the prescription period (i.e. one month) having reference to all cannabinoids and all forms used, prescriptions issued and licensing terms; [See: "Quantity of Medicinal Cannabis to be Supplied and Possessed" in this submission.]

30. separate prescriptions for different forms of cannabis and administration methods ensure:

- accurate dosage for patieont's;
- the avoidance of errors by a doctor or the Medicinal Cannabis Practitioner in dosing which might leave the patient without sufficient medicine; and
- makes dispensing and tracking of cannabis provided to the patient's easier and reflects current pharmacy practices in the dispensing of medications.

31. the prescription form to be completed by the treating practitioner would be housed in and issued from an electronic database operated by the relevant Victorian Government or department responsible for administering the scheme. The prescription would be completed online by the medical practitioner via a special portal accessed by using the practitioners AHPRA license registration and/or other registration code provided and issue by the Victorian Government for the purposes of the scheme. The prescription would be automatically saved on the electronic database. A hard copy could be printed and given to the patient and or their carer. The prescription remains on the electronic database where restricted access to it would be available to other medical practitioners, hospitals, Medicinal Cannabis Dispensaries and Medicinal Cannabis Practitioners involved in the patients medical treatment and care involving medicinal cannabis under the operation of the scheme;

32. in addition to the information provided at paragraph 29, the following information would be required to complete the electronic prescription:

- practitioners AHPRA professional license code and / or any other code issued under the medicinal cannabis scheme;
- patient details: name, address, date of birth;
- patient's personal identification number from their Medicinal Cannabis Card; [See: "Medicinal Cannabis Cards & Licenses" in this submission.]
- date of prescription; and
- expiry date of prescription (end of 12 months);
- number of repeats (5 as for standard medications associated with chronic medical conditions);

33. should a patient require an increase in their daily prescribed dose[481], the medicinal practitioner would issue a new prescription with a new TDD and or MTDD (where applicable). This may be required at times of stress or additional illness, which may lead to a further exacerbation in symptoms and/or health complications. An alteration to a patients MTDD would require an amendment to the patients treatment plan and lodgement with the electronic data base operated by the Victorian Government for the purposes of the scheme;

34. prescriptions should be valid for 12 months as is customary with prescriptions for registered medicines No repeat on initial prescription(s) would be issued unless and/or until the treating and prescribing practitioner is satisfied with the patient's ability to manage dosage and / or any undesired side effects;

35. in some jurisdictions, there are no limitations on the prescribed daily dose. This submission supports this approach. Patients are currently prescribed a quantity of standard pharmaceutical medications to a level necessary to give relief and/or address their pain and suffering. Accordingly, there is no justification to deny such to a medicinal cannabis patient. Further, it is considered that under the proposals advocated by this submission, there would be sufficient checks and balances to ensure that medicinal cannabis use is not open to misuse;

36. some jurisdictions that do not or cannot offer cannabis under prescription, place limitations on the quantity of cannabis that a patient can have in their possession at any one time and usually enough medicine to last them between a 30 to 90 day period. In Canada, the quantity of medication a patient can have access to over the stipulated period is referenced to the patient's daily dose of medication;

37. the operation of a prescription based system of the nature suggested, would negate the requirements referred to at paragraph 36 above. A prescription in association with a patients license(s) issued by the Victorian Government agency or relevant department, would determine the lawful quantity a patient could have in their possession over the life of the prescription i.e. 30 days;

38. Adopting a prescription approach would meet a number of identified Regulatory Objectives referred to in this submission and would further:

- ✓ ensure that all patients have a precise and adequate quantity of medication to address their individual biological and therapeutic needs;
- ✓ ensure that all patients have a continuous supply of medication;
- ✓ provide checks and balances between prescribing and dispensing practitioners;
- ✓ provide checks and balances to ensure that medicinal cannabis is dispensed strictly to those licensed under the scheme;
- ✓ enable General Medical Practitioners and/or Medicinal Cannabis Practitioners the flexibility to prescribe at shorter intervals (14 days) at the outset of treatment (if required) in order to monitor patients with no prior exposure to cannabis and/or low tolerance levels and/or for those patients identified as vulnerable or at risk;
- ✓ ensure that the patient returns to their General Medical Practitioner or Medical Cannabis Practitioner for regular review and monitoring;
- ✓ provide a means of monitoring a patients medicinal cannabis use, general health and therapeutic outcomes;

The medicinal cannabis scheme supported by this submission also cross references the prescription process with:

- cultivation licenses and Medicinal Cannabis Cards; and
- the permitted quantity of cannabis a patient may cultivate and or have in their possession.

The Commission is referred to " Medicinal Cannabis Cards & Licenses" and "Quantity of Medicinal Cannabis to be Supplied and Possessed" in this submission.

This meets a number of further Regulatory Objectives identified in this submission including:

- ✓ assisting in determining the quantities of medicinal cannabis demanded and/or in supply through out Victoria during any one period in time, which would be required by regulators in issuing of commercial cultivation licenses;
- ✓ assisting in ascertaining the quantities of medicinal cannabis demanded and/or in supply through out Victoria during any one period in time, enabling regulators to examine the performance of the scheme with a view to improving the same;
- ✓ assisting regulators in examining prescription data associated to quantities and particular strains of cannabis being supplied to patients under prescription. This data could be collated, examined and/or used for regulatory and or medical and scientific research purposes;
- ✓ provides a regulatory means of monitoring supply, use, misuse and possible diversion to the illicit market by all licensed persons and/ or entities under the scheme;

39. and notes the Commission's comments that the role of the doctor within the operation of a medicinal cannabis scheme would be ''complex'' because:

- of conflicting claims about therapeutic benefits of cannabis;
- limitations in knowledge about side effects; and
- risk of diversion to the illicit market.

40. in so far as this comment may also broadly relate to Medicinal Cannabis Practitioners proposed under this submission:

a) the Commission is referred to the "Safe and Effective Use" of Cannabis in this submission;

b) believes an appropriately regulated system will, with its incorporated checks and balances, adequately address concerns of ''potential'' ''risks'' for diversion and largely preclude the same. No regulatory system is flawless and there is always a margin for unlawful operations within them. However, the overall benefits of such regulatory systems outweigh this small risk. Revocation of licenses under a scheme and/or the threat of: a patient losing access to their medicine; the loss of professional licenses and associated businesses operating within the scheme; together with legal sanctions, would operate as strong deterrents. Law enforcement operates as an adjunct to all regulatory systems and a proposed medicinal cannabis system would be no different in that regard. The risk of diversion of medicinal cannabis to the illicit market from a controlled and regulated scheme of the nature being proposed, with it's many checks and balances, is probably far less likely than currently exists under the current scheme operating in relation to prescription pharmaceuticals. The health and human rights of patient's must not be sacrificed because of a small risk of diversion to the illicit market under such a scheme;

c) notes that there is a large body of conflicting scientific literature on a large number of existing approved therapeutic goods. Not all side effects of approved therapeutic goods are known at the time of approval for a registered medicine, as only those identified at the time of clinical trials and or those that come to light prior to the registration process are known, if they are in fact submitted.[482] This is particularly problematic with novel therapeutics. To illustrate this point further, there are a number of pharmaceuticals that produce side effects, complications and serious threats to health requiring product withdrawal and or the issue of guidelines for contraindicated uses, sometimes years after their regulatory approval. Between 2005 and 2012, the FDA approved 188 novel therapeutic agents for 206 indications on the basis of 448 pivotal efficacy trials.[483] The median number of pivotal trials per indication was two, although 74 indications (36.8%) were approved on the basis of a single trial;[484]

   A far greater number were approved despite contradictory trial outcomes and only about 40 percent of those were compared to drugs currently being prescribed.[485] We can therefore say, that the therapeutic value and the knowledge of side effects for many registered medicines approved for use today, are limited. Such has not precluded these medicines being prescribed. It is hard to see how much more ''complex'' introducing cannabis into this current picture could be.

Scientific research[486] has also shown that drugs prescribed on a very regular basis averaged around 100 side-effects each, with some reaching 525 negative reactions. Few studies are done on how these substances interact with one another.

In contrast, cannabis has a short list of known side effects. In examining it's safety profile, Judge Francis Young of the USA's Drug Enforcement Administration at the end of a lengthy 2 year legal enquiry in which this issue was under consideration concluded: "Marijuana in its natural form is one of the safest therapeutically active substances known to man". He recommended that medical use of cannabis should be allowed[487]

When used judiciously, the safety profile for cannabis consumption is considered to be very good[488]and the general adverse effects have been stated to be tolerable and not

unlike those seen with other medications.[489]

Cannabis however, is not a novel therapeutic. It has been used for thousands of years and over that period, there has not been one reported death directly attributed to its use[490]. It has been successfully used in a medical setting under the supervision of treating doctors in overseas jurisdictions for more than 25 years.

Finally, any confusion and concerns regarding the medicinal use of cannabis and its side effects can be easily assuaged by reminding doctors that whole plant based medicinal cannabis is currently an approved TGA schedule 8 substance under the Poisons Standard in the from of a Sativex oral mucosal spray.

41. the Commission reference to the possible need for additional clinical measures to maintain control over the use of medicinal cannabis including the following:

a) authorising only certain categories of specialist medical practitioners to assess whether the patient meets the eligibility criteria;

b) setting out procedures that a practitioner should follow when making an assessment;

c) requiring two medical practitioners to certify that a patient would receive (substantial) therapeutic or palliative benefit from medicinal cannabis;

d) limiting the period of authorization and or requiring that patient's return to the medical practitioner at regular intervals; and

e) requiring certification from the medical practitioner that there is a bona fide doctor-patient relationship with a person whom they have assessed.

42. this submission agrees with the suggestions at paragraph 41 b) above, in so far as such relates to Medicinal Cannabis Practitioners;

43. providing education on the nature and benefits of cannabis, the endocannabinoid system, its forms, safe use and administration, together with the operation of a medicinal cannabis scheme and a doctors role in it, should be mandatory as part of a medical practitioners continuing medical education and as part of the renewal of their professional licensing requirements. Such a requirement should over time, encourage further participation of General Medical Practitioners in the operation of a medicinal cannabis scheme;

44. this submission agrees in principle with the suggestion at paragraph 41 d) above that a patient using medicinal cannabis should return to their treating practitioner shortly after commencing medicinal cannabis therapy for the purposes of a review. In terms of limiting the period of authorisation, this submission supports:

- the operation of prescriptions for a period of 12 months and that
- that licenses be renewed every 12 months.

45. this submission does not support the suggestions at paragraph 41 a), c) and e) above. This will limit a patient's timely access to medicinal cannabis and may, due to costs associated with the exercise, deny a patient access entirely. As stated previously, a consultation with a specialist physician can cost between $270 to $700 an hour.[491]

Patient's on average may be required to wait in excess of 8 weeks to see one specialist physician. What would constitute a bona fide or established relationship with a patient would also be a subjective and left open to the interpretation of each physician. This may result in a physician determining to treat a patient for longer than is necessary at considerable cost, delay and suffering to the patient. There have been reports of physicians in overseas jurisdictions expressing the view that anything less than a relationship of 2 years, is not viewed by such physicians as an authentic or bona fide physician/patient relationship. The suggestion is impractical for the terminally ill and or those patient's desperate for relief from debilitating symptoms. As acknowledged by the Commission in this issue paper, jurisdictions such as Vermont in the USA, have attempted to address this by defining a bona fide patient / physician relationship as one where the treating or consulting relationship has been in place for a minimum period of 6 months. Patient's with cancer, HIV/AIDS, and the terminally ill, have been rightly exempt from this requirement in that jurisdiction. The suggestions offered by the Commission were initially promoted by Health Canada and were not embraced by patients due to the difficulties identified. Patient's found it much easier to return to the illicit market. Health Canada subsequently amended the requirements referred to at paragraph 38 a), c) and e) above, and replaced it by leaving the relevant determination to be made by a patient's General Medical Practitioner, exercising his or her discretion; [492]

46 the suggestions at paragraph 41 a), c) and e) above, are considered to be contrary to the stated Regulatory Objectives of this submission for a proposed medicinal cannabis scheme;

47. the approach of Oregon, USA referred to in the issue paper, appear to align more closely with the stated Regulatory Objectives identified in this submission for a proposed medicinal cannabis scheme. In Oregon, USA, a doctor may authorise a patient to have access to their medicinal cannabis scheme once they have:

- reviewed a patient's medical records;
- conducted a through physical examination of the patient;
- provided or planned a follow up consultation; and
- documented each of these activities in a patient's file.

PART EIGHT

CULTIVATION PROCESSING & THE DISTRIBUTION OF MEDICINAL CANNABIS

CULTIVATION PROCESSING & THE DISTRIBUTION OF MEDICINAL CANNABIS

It is acknowledged and/or submitted that:

1. cultivation, possession, processing, preparing or manufacturing cannabis or cannabis products for the purposes of trafficking is prohibited in Victoria unless authorised by the Drugs, Poisons and Controlled Substances Act 1981 (Vic) or regulations;

2. the Victorian government can amend the Drugs, Poisons and Controlled Substances Act 1981 (Vic) independently of the Commonwealth to permit Victorians to attend to such activities that might be associated with cannabis for medicinal use; and

3. in doing so Victorians would be provided with a defence in relation to prosecutions under the Commonwealth Criminal Code Act 1995;

4. a complete exemption from prosecution is desirable rather than having to rely on a defence. Reliance on a defence, as distinct to a complete statutory exemption from prosecution, does not accord with the Regulatory Objectives identified in this submission. Such would require co operation between the State and Commonwealth Government;

5. Victorians may still require a manufacture license to comply with the Commonwealth Narcotic Drugs Act 1967;

6. the Narcotic Drugs Act 1967 (Cth) seeks to give effect to the United Nations Single Convention on Narcotic Drugs 1961 (''the Convention"). The Convention acknowledges that cannabis or resin separated from the plant constitutes ''production'', with everything else stemming therefrom constituting ''manufacture''. To produce cannabis products and/or package and or distribute them may be considered to ''manufacture'' and therefore subject to licensing requirements under the Act;

7. if an amendment to the Act (to exempt the issue of a manufacturing license for the purposes of a medicinal cannabis scheme with the co-operation of the Commonwealth) is not possible, an amendment to the Act and / or an agreement between the State and Commonwealth Government might be reached, to enable the Victorian Government to issue the license contemporaneously with a cultivation license. This might be permitted via a delegation of such a power to the Victorian State Government under S.25 of the Narcotic Drugs Act. 1967 (Cth) or under regulations, an appropriate amendment to such legislation to allow the same;

8. in the interim, participants of the scheme may require a manufacturing license from the Commonwealth Government and meet the requirements set out in the Commonwealth legislation regarding the manufacture of narcotic drugs;

9. the application national therapeutic goods administration scheme to the cannabis plant is questionable and/or alternatively should the scheme apply, amendments to the scheme could be made to remove the cannabis plant from its operation for the purposes of a medicinal cannabis scheme. This submission proceeds on this basis and;

10. in the same way the Victorian Government regulates the Victorian opium industry by sharing responsibilities with the Commonwealth, similar arrangements could be made

with respect to the cultivation, processing manufacture and distribution of medicinal cannabis with appropriate legislative amendments and/or further legislation and/or regulations;

11. that such regulations would need to accord to the Regulatory Objectives identified in this submission and might broadly include the following:

    - license application criteria;
    - authorised participants within a scheme and issuing relevant licenses;
    - quantities of plants that may be permitted to be grown and in cultivation at any one time by the holders of authorised licenses;
    - access to seeds for cultivation and any requirements associated with the same;
    - quality assurance standards and regulations associated to cultivation, production, processing, handling, supply, transit, sale and storage of cannabis and cannabis products;
    - quality assurance standards and regulations associated with the distribution and sale of cannabis/cannabis products/paraphernalia including distribution premises, distribution methods, labelling and advertising; and
    - regulations providing for the testing of cannabis and cannabis products for composition, potency and quality at suitably accredited laboratories.

12. that the advantages of regulation with regard to cultivation, processing and distribution include:

    - impact on quality of cannabis & cannabis products;
    - confidence of consumers, Medicinal Cannabis Practitioners, and dispensaries as to composition and constitution of cannabis produced; and
    - confidence and support of the general public in a medicinal cannabis scheme.

MEDICINAL CANNABIS CARDS & LICENSES

1. This submissions favours the use and adoption of a Medicinal Cannabis Card as a feature of a proposed medicinal cannabis scheme.

2. On the basis of comments made at "A Regulatory Framework for a Medicinal Cannabis Scheme'' in this submission, a patient, parent, guardians an/or carer would make application to the relevant Victorian Government agency or department established to administer the scheme for appropriate Victorian and Commonwealth licenses. These licenses would issue simultaneously in the form of a Medicinal Cannabis Card.

3. Medicinal Cannabis Card's would meet the stated Regulatory Objectives referred to in this submission serving the needs of multiple stakeholders including:

    - licensed General Medical Practitioners;
    - Medicinal Cannabis Practitioners;
    - Medicinal Cannabis Dispensary Practitioners;
    - Compassion Club operators;
    - cultivators
    - regulators and
    - law enforcement officers.

4. Under the proposed medicinal cannabis scheme favoured by this submission, medicinal cannabis and cannabis products would be made available:

    - on prescriptions issued by General Medical Practitioners or Medicinal Cannabis Practitioners registered and given prescribing rights for the purposes of the scheme; [See: "Authorizing and Prescribing Medicinal Cannabis" in this submission.] and

    - dispensed at a Medicinal Cannabis Dispensary on presentation of an Authority to Possess License or APL in the form of a Medicinal Cannabis Card;

    - under the operation of a "Personal Production License" or "PPL" which would permit a patient to cultivate and harvest a specified quantity of medicinal cannabis; [See: "Cultivation: Personal Production" in this submission.]

    - under the operation of an "Authority to Designate Production under License" or "DPL (A)" to a third party to cultivate and harvest a specified quantity of medicinal cannabis on the patients behalf. ["Cultivation: Designated Production and Third Party Cannabis Producers" in this submission]

5. It is proposed that a Medicinal Cannabis Card could:

    - in and of itself, constitute a license to possess, use, manufacture, administer and /or supply cannabis by/or for a patients medicinal use and needs. This is referred to for the purposes of this submission as a "Authority to Possess License" or "APL";

    - as an APL, authorise a holder to obtain and possess medicinal cannabis and cannabis products on prescription at a Medicinal Cannabis Dispensary;

- where the card carries a reference code to personally cultivate cannabis under a Personal Production License or PPL constitute lawful authority to possess, manufacture, administer, cultivate, supply and or sell cannabis for medicinal purposes;

- where the card carries a reference code for the card holder to lawfully engage a third party cultivator under an Authority to Designate Production under a License or DPL (A), constitute lawful authority to possess, manufacture, administer, cultivate via third party, supply and or sell cannabis for medicinal purposes;

- be relied upon as evidence of the lawful authorities referred to and noted on the card, removing the threat of legal process and prosecution. Such would be deemed to take effect upon issue of the Medicinal Cannabis Card;

- identify the nature (i.e. patient card, guardian or carer) of the card. A duplicate card could issue to a patients parent, guardian or carer, identifying the cardholder's relationship to the patient. These parties could also be registered participants under the scheme and their details recorded in an electronic data base established by the Victorian Government for administration of the scheme;

- note all licenses held by the card holder where the party in question holds more than one license;

- constitute evidence of all license(s) noted on the card and issued to the card holder under the scheme;

- be used to obtain a prescription for medicinal cannabis;

- be used to have a prescription filled for medicinal cannabis and or cannabis products at a Medicinal Cannabis Dispensary;

- be used to apply for additional licenses, (if required and where the same are not issued simultaneously with the Medicinal Cannabis Card);

- hold a passport size photograph of the card holder and could be used to identify the card holder as a registered lawful participant under the scheme and could be provided to the following:

    - General Medical Practitioners or Medicinal Cannabis Practitioners;
    - Medicinal Cannabis Clinics and Medicinal Cannabis Dispensaries to access services and medication on prescription;
    - Compassion Clubs;
    - Commercial Producers cultivating for a patient under a DPL;
    - Employers;
    - Real Estate Agents (rental circumstances);
    - Day Care Centres;
    - Schools;
    - Hospitals;
    - Municipal Council Officers;
    - Law Enforcement Officers.

- be valid for 12 months.

6. All Medicinal Cannabis Cards issued under the scheme favoured by this submission would represent an Authority to Possess License or APL. Any and all additional licenses could be noted by on the Medicinal Cannabis Card with an appropriate reference code.

7. An APL in the form of a plain Medicinal Cannabis Card would be required by:

   (i) all patients under the scheme;

   (ii) all patients requiring access to medicinal cannabis under prescription;

   (iii) patients requiring cultivation licenses [PPL or DPL(A) by an individual or commercial producer under a DPL] to ensure a continuous supply of medication to cover the period for planting to harvest/drying/curing of a crop; and/ or

   (iv) those patients holding one or more licenses electing to take a percentage of their Maximum Total Daily Dose ("MTDD") of medicinal cannabis to be divided across all licenses held including a APL.

   Patients who may need to cultivate cannabis directly under a PPL or via an individual or commercial producer under a DPL (A) would require access to medication for approximately 4 months until their own crops have been harvested, dried and cured. Consequently, all patients entering the scheme favoured by this submission would require an APL/Medicinal Cannabis Card to ensure they receive a continuous source of medication.

8. In addition to an APL/Medicinal Cannabis Card, one or more of the following additional licenses may be required and held by a patient or parent, guardian or carer:

   (i) a "Personal Production License" or "PPL"; and/or

   (ii) an "Authority to Designate Production under a License" or "DPL (A)" to engage an:

      - Individual; and/or
      - Compassion Club or Co-Operative; and/or
      - Commercial producer;

      to grow cannabis under an "Designated Production License: ("DPL") up to the quantity permitted under the terms of the license;

   (iii) both a PPL and one or more DPL (A)'s to have one or more of the identified third parties cultivating cannabis on their behalf.

9. There are a large variety of highly individualised circumstances where a patient may require more than one license which might include:

   (i) economic, physical or geographical constraints;

(ii) specific cannabinoid/terpene requirements and the inability to access a specific required cannabis strain to address a specific medical need;

(iii) limitations associated with a cultivation site and or limitations associated with cultivation capacity;

(iv) the need for a mix of cannabis strains and/or products from a variety of sources to meet a variety of medical needs;

(v) a combination of the above.

For example it might be envisaged that:

,

- for economic and physical disability considerations a percentage of a patients required medicinal cannabis may need to be supplied under a PPL, with the remainder to be supplied by speciality products (i.e. edibles or extracts) on prescription under a APL/Medicinal Cannabis Card; or

- for specific medical and economic needs, a percentage of a patients required medication may need to be cultivated and supplied by a Compassion Club under a DPL (A) with the remainder to be sourced from a specific strain of cannabis being cultivated especially for the patient's medical condition by an individual specialising in the cultivation of the strain in question or a commercial producer operating under DPL; [See: "Cultivation: Designated Production and Third Party Cannabis Producers" in this submission.] or

- a patient living in rural Victoria may suffer from chemical sensitivities and requires that cannabis be directly under a PPL. Due to limitations associated with the cultivation capacity of the patients cultivation site and the inability of the patient to access a Compassion Club due to the patients rural location, the patient could engage an individual under a DPL(A) to cultivate the remaining quantity of cannabis to cover the patients Maximum Total Daily Dose of medication;

- for economic considerations, a patient requires that 50% of the patients Maximum Total Daily Dose ("MTDD") of medication is to be cultivated indoors under a PPL, with the remainder of the MTDD to be divided by taking 40% of more affordable medication from a Compassion Club under a DPL(A) on prescription and the remaining 10% to be by supplied on prescription by a Medicinal Cannabis Dispensary carrying a speciality product or strain not otherwise available to the patient.

It is important that a medicinal cannabis scheme be flexible enough to meet the varying medicinal needs and individual circumstances of patients. The issue of more than one license under a scheme of the nature favoured by this submission would be vital to ensuring that a patient had access to sufficient and appropriate strains of medicinal cannabis to meet their individualised medical, economic and personal needs.

10. Under the scheme favoured by this submission it is envisaged that upon application for a Medicinal Cannabis Card a patient, parent, guardian or care provider would:

10.1 Identify one or more of the following as the sources of medicinal cannabis to be supplied to the patient:

- Medicinal Cannabis Dispensaries;
- a Compassion Club or Co-Operative under a DPL (A);
- an Individual under a DPL;
- a Commercial producer under a DPL;
- a Personal cultivation under a PPL;
- a combination of the above.

10.2 state the percentage of the Maximum Total Daily Dose of medicinal cannabis to be obtained from the sources referred to and the duration of the license period. For example:

- 100% of the permitted quantity of medicinal cannabis to be acquired on prescription under a APL via Medicinal Cannabis Dispensaries over a 12 month period; or

- 100% of the permitted quantity of medicinal cannabis is to be acquired on prescription under a DPL (A) via a Compassion Club with a dispensary over a 12 month period; or

- 100% of the permitted quantity of medicinal cannabis is to be acquired on prescription under an APL at a Medicinal Cannabis Dispensary for 4 months (cultivation/drying period) and 100% to be acquired under a PPL for 8 months thereafter; or

- 100% of the permitted quantity of medicinal cannabis is to be acquired on prescription under an APL at a Medicinal Cannabis Dispensary for 4 months (cultivation/drying period) with 50% to be acquired from the harvest of a crop under a PPL and 50% via a APL on prescription at a Medicinal Cannabis Dispensary for 8 months thereafter; or

- 100% of the permitted quantity of medicinal cannabis is to be acquired on prescription under an APL at a Medicinal Cannabis Dispensary for 4 months (cultivation/drying period) with 50% to be acquired from the harvest of a crop under a PPL and 25% via a commercial producer providing a special strain of cannabis under a DPL (A) and DPL, with the remaining 25% under an APL on prescription at a Medicinal Cannabis Dispensary for cannabis edibles, for 8 months thereafter.

10.3. where cultivation licenses are sought [i.e. PPL or DPL(A)] whether:

- cultivation is to take place indoors, outdoors or in combination (but not simultaneously);

- whether cultivation is to take place entirely outdoors with an intention to cultivate 12 months in advance [See: Cultivation: Personal Production and

"Quantity of Medicinal Cannabis to be Possessed and Supplied" in this submission.];

10.4 The measure at paragraph 10.1 and 10.3 would assist the relevant Victorian Government agency or department(s) to:

- identify the quantity of medicinal cannabis required by Victorian patients over a 12 month period;
- calculate the quantity of cannabis to be cultivated under individual licenses applied for or on behalf of a patient;
- calculate the quantity of cannabis that could be cultivated under Commercial Production Licenses;
- determine the total number of Commercial Production Licenses that could operate in Victoria within a 12 month period;
- monitor and regulate participants under the scheme;
- collate data to review and improve the operation of the scheme.

10.5 have a General Medical Practitioner or Medicinal Cannabis Practitioner complete and lodge with the electronic database operated by the Victorian Government for the purposes of the scheme:

(i) a certification stating that a patient is eligible to be treated with medicinal cannabis; and

(ii) details of a patients Maximum Total Daily Dose of cannabis medication as set out in a patients medicinal cannabis treatment plan created by the practitioner;

10.6 lodge the following information with the relevant Victorian Government agency or departments established for the scheme:

- patients full name, age, date of birth and sex;
- patients address;
- a passport photo for adhering to a Medicinal Cannabis Card;
- how medicinal cannabis will be sourced; [See: paragraph 10 (i) above]
- what percentage of the medicinal cannabis is to be obtained from the sources identified; [See: paragraph 10 (ii) above.]
- additional license(s) being sought and whether cultivation is to be indoors, outdoors or a combination and over what period of time
- the location and address of the premise(s) at which Medicinal Cannabis will be stored;
- a copy of a valid medical or enduring Power of Attorney (where relevant)

10.7 lodge the following information (where applicable) with the relevant Victorian agency or government departments established for the scheme:

- a patient's parent, guardian, carer's full name, age, date of birth, sex and address and contact details;
- a passport photo for adhering to a Medicinal Cannabis Card
- In addition for a carer:

- their relationship to the patient:
- premises or location(s) at which medicinal cannabis will be stored and / or used (i.e. school, crèche, nursing home, hospital, retirement home);
- a copy of a valid medical or enduring Power of Attorney (where relevant);

10.8 A patient's Medicinal Cannabis Card would contain the following information for APL, PPL & DPL (A) licenses:

- patients full name, sex, age and date of birth
- patients residential address;
- date of issue and date of expiry;
- type of license(s) held; i.e. APL, PPL, DPL;
- patient identification number for the purposes of the scheme;
- passport size and appropriate photograph of the patient;
- any special code related to any specific license conditions.

10.9 A Medicinal Cannabis Card issued to a patient 's parent, guardian or authorised care provider(s) would contain the following information:

- parent, guardian or carer's full name, sex, age and date of birth;
- residential address; or
- address of site at which medicinal cannabis is to be supplied, administered or otherwise used. i.e. school, crèche, nursing home;
- date of issue and date of expiry;
- type of license(s) held by the patient and or guardian i.e. APL, with a code (g) to denote guardian and (c) for care provider – i.e. APL (c);
- registration or identification number for the purposes of the scheme that could be linked back through the electronic data base to the patients Medicinal Cannabis Card;
- passport size and appropriate photograph of the card holder.

11. In Canada, Medicinal Cannabis Cards for parties holding cultivation licenses also contained the following information:

- the address of the premises at which cannabis is to be cultivated;
- the maximum number of plants permitted to be grown indoors or outdoors or a combination of both and number allowed for each;
- maximum amount of cannabis permitted to be stored under a storage quota;
- the address of the premises at which the medicinal cannabis is to be stored.

This submission does not favour disclosing such information on a Medicinal Cannabis Card**.** Although there has been no real evidence of home invasions and/or crop thefts of persons operating under Personal Product Licenses in Canada[493], the publication of such details on a Medicinal Cannabis Card is likely to expose the cardholder to an increased possible risk of home invasion and crop theft. As these details would be securely housed within the electronic data base operated by the Victorian Government for the purposes of the scheme, with law enforcement officers having access to such information, there appears to be no real need for the data to appear on the card itself.

12. Revocation of a APL and/or a Medicinal Cannabis Card with other license might occur where:

- the license holder requests the revocation;
- the license holder was not eligible for entry to the scheme;
- a General Medical Practitioner or Medicinal Cannabis Practitioner advises the relevant Victorian Government agency or department that there is no valid certification in operation;
- an act or omission of the license holder has triggered the revocation of any license held and denoted on the card. In such circumstances, a new card (if and where appropriate) would issue with the remaining licenses noted;
- a license was obtained on false or misleading information;
- the photograph submitted for the purposes of the license is not an accurate representation of the card holder;
- a card holder has failed to notify a local law enforcement agency within 24 hours and the relevant Victorian Government agency or department (s) in 72 hours of any theft of medicinal cannabis;
- a card holder has failed to notify a local law enforcement agency within 24 hours and the relevant Victorian Government agency or department (s) within 72 hours of an entire destruction of a medicinal cannabis crop or permitted storage quota of medicinal cannabis;
- a card holder has failed to notify the relevant Victorian Government agency or department (s) of a change in the holders name, address, site production or storage location together with proof of the same.

13. Revocation of a Medicinal Cannabis Card would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and

- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process;

14. Where a license and/or Medicinal Cannabis Card is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return their license/Medicinal Cannabis Card within 30 days of receiving the notice referred to at paragraph 13 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively;

15. Where a license / Medicinal Cannabis Card holder wishes to challenge the reasons for the revocation, forfeiture of the license/Medicinal Cannabis Card would take place at conclusion of any review or appeal process, where the outcome did not favour the license/card holder. It is important that the license/Medicinal Cannabis Card holder have access to medicine until all claims concerning the revocation have been heard and definitively determined. Anything short of such could amount to a breach of a patients fundamental Human Rights;

QUANTITY OF MEDICINAL CANNABIS TO BE SUPPLIED & POSSESSED

It is acknowledged and/ or submitted that:

1. the quantity of medicinal cannabis in supply in the community and/or in the possession of the patient at any one time is regulated in medicinal cannabis schemes currently in operation in overseas jurisdictions;

2. the quantity of medicinal cannabis in supply in the community at any one time is generally controlled by licensing stipulations and regulation;

3. any proposed scheme should ensure that the quantity of medicinal cannabis cultivated can be calculated to meet the total medicinal needs and demand of patients. This would therefore minimise any surplus and possible diversion to the illicit market;

4. quantifying and regulating the quantity of cannabis in supply within the community under the medicinal cannabis scheme proposed by this submission can be achieved by:

4.1 identifying sources from which patients intend to obtain their medicinal cannabis from at the time of making an application for a Medicinal Cannabis Card, thus enabling a determination of how much cannabis would be required to be commercially cultivated; [See: "Medicinal Cannabis Cards and Licenses" in this submission.]

4.2 a General Medical Practitioner or Medicinal Cannabis Practitioner submitting details to the relevant Victorian Government agency or department administering the scheme of the patients Maximum Total Dose ("MTDD") of cannabis medicine set out in a patients treatment plan. This information would be used to ascertain and limit the quantity of medicinal cannabis in the community as well as the quantity a patient can have in their possession at any one time:

a. under prescription:

(i) by reference to the patients Maximum Total Daily Dose of cannabis medicine multiplied by the duration of the prescription (i.e. total of 5 grams per day x 30 days (prescription duration) = a total of up to 150 grams of medicinal cannabis could be possessed at any one time); or

b. under a PPL, or DPL(A) and DPL, quantifying and limiting the amount of cannabis in cultivation:

(i) using a mathematical equation and a patients Maximum Total Daily Dose ("MTDD") of medicinal cannabis to calculate and limit the number of seeds, clones, juvenile plants and flowering plants required by a patient to cover their medicinal needs over a period of 12 months or less; and

(ii) limiting the number of crops that can be cultivated over a 12 month period; and

(iii) not permitting the simultaneous cultivation of indoor and an outdoor crop; and

(iv) limiting the quantity of medicinal cannabis a patient may retain and

store from a crop's yield; ("storage quota") having reference to a mathematical equation involving:

- a patients Maximum Total Daily Dose ("MTDD") of medicinal cannabis; and
- the number of seeds, clones, juvenile plants and flowering plants permitted to be cultivated; and
- a deemed yield for a plant grown indoors and a plant grown outdoors.

4.3 making provision tor the sale, donation or disposal of any unexpected crop yield over the permitted storage quota stipulated under a patients license.

5. overseas jurisdictions do not customarily offer medicinal cannabis under the operation of a prescription. The regulations of these schemes stipulate the quantity of medicinal cannabis that a patient may have in their possession at any one time by reference to:

a) the quantity by weight; and / or

b) a patient's daily medicinal dose; and

c) over a nominated period of time i.e. 30 days.

For example: A patient taking a Maximum Total Daily Dose of 5 grams of cannabis a day, would be permitted to have up to 155 grams of cannabis in their possession at any one time over in a thirty day period. The total quantity of cannabis permitted to be possessed by a patient in these jurisdictions is dependant on the total number of days specified by the regulations of these schemes, which varies from 30 to 90 days.

6. This submission supports the issue of medicinal cannabis on a prescription basis, where it is proposed that:

- General Medical Practitioners and Medicinal Cannabis Practitioners be provided with prescribing rights for the purposes of the scheme;
- prescriptions would be accessed and completed by the treating practitioners from the electronic data base operated by the Victorian Government for the purposes of the scheme. Medicinal Cannabis Dispensary Practitioners would also access the electronic data base to check the prescription issued; [See: "Authorizing and Prescribing," "Medicinal Cannabis Clinic's" and "Medicinal Cannabis Dispensaries" in this submission.]
- a copy of a prescription would be issued to a patient;
- prescriptions would incorporate the information referred to at paragraph 4 (2) (a) & (b) above in addition to the details referred to at "Authorizing and Prescribing" in this submission;
- the prescription would be valid for a 12 month period;

- the prescription period would be for 30 days, with up to 5 repeats consistent with current prescribing practices for general pharmaceuticals. This would address the inconvenience and the expense associated with obtaining regular prescriptions from a General Medical Practitioner;

- repeats on prescriptions for medicinal cannabis might be considered appropriate for patients who:

    - are travelling;
    - are immobile;
    - live in rural and remote regions; or
    - may, due to other health limitations find it difficult to make regular physical attendances at their practitioner's clinic.

- a shorter prescription period of 14 days could be issued for patients commencing medicinal cannabis therapy with no prior exposure and low tolerance levels, until such time as the patient manages their dosage;

- the Maximum Total Daily Dose of medicinal cannabis or quantity of medicinal cannabis to be prescribed would be left to the discretion of the prescribing practitioner, the details of which would have been submitted to the relevant Victorian Government agency or department upon application for a Medicinal Cannabis Card and relevant licenses under the scheme;

- medicinal cannabis would be dispensed under prescriptions completed by a General Medical Practitioner or a Medicinal Cannabis Practitioner via an online electronic platform of the electronic data base operated by the Victorian Government for the purposes of the scheme; [See: Authorizing and Prescribing" in this submission.]

- a patient would require a valid Authority to Possess License or APL (a valid Medicinal Cannabis Card) to have the prescription issued and filled;.

- medicinal cannabis would be dispensed by a licensed Medicinal Cannabis Dispensary and Medicinal Cannabis Dispensary Practitioner; [See: "Processing and Distribution: Medicinal Cannabis Dispensaries" in this submission.]

- Medicinal Cannabis Dispensary practitioners would have access to the electronic data base established by the Victorian Government for the purposes of the scheme to check all prescriptions as well as the Maximum Total Daily Dose ("MTDD") of medicinal cannabis a patient has been permitted and what percentage of that quantity the patient has elected to have filled on prescription; [See: "Processing and Distribution: Medicinal Cannabis Dispensaries" in this submission.]

- medicinal cannabis and cannabis products would be dispensed by a licensed Medicinal Cannabis Practitioner in accordance with the terms of a valid prescription and the terms of a valid APL or Medicinal Cannabis Card; ["Processing and Distribution: Medicinal Cannabis Dispensaries" in this submission.]

- the total quantity of medicinal cannabis that could be dispensed by a licensed

Medicinal Cannabis Dispensary Practitioner would be determined by:

- the terms of a valid prescription; and
- the percentage of a patients Maximum Total Daily Dose that is to be filled on prescription as set out under the terms of a patients APL or Medicinal Cannabis Card;

➢ the total quantity of medicinal cannabis a patient could have in their possession at any one time would be:

- the Maximum Total Daily Dose ("MTDD") of medicinal cannabis set out in a patients treatment plan; and
- where the patient holds more than one license under the scheme, the percentage of their MTDD spread across and as set out under the terms of the licenses held;

For example:

A patient has a MTDD of cannabis at 10 grams a day specified in the treatment plan formulated by their treating practitioner. The patient holds an APL and PPL.

Under the terms of the APL and PPL issued to the patient the patient elected to receive 100% of their medicinal cannabis on prescription for a 4 month period or up until the patients cannabis crop had been harvested, dried and cured ("the harvest period"). At the conclusion of this period and for the remaining 8 months, the patient elected to receive 50% of their medicinal cannabis needs (or 50% of their MTDD) from the permitted storage quota of their harvested crop and the remaining 50% on prescription under their APL;

The total quantity of medicinal cannabis a patient could have in their possession at any one time would be:

- for the first 4 months: up to 300 grams over 30 day prescription period and for 8 months thereafter:
- up to 150 grams over a 30 day prescription period on each repeat prescription; and
- a quantity of cannabis harvested under a PPL on the basis of a mathematical equation which calculated and permitted the patient to cultivate a specific number of flowering plants and store a quantity of cannabis to cover a Maximum Total Daily Dose of 5 grams of medicinal cannabis over the 8 month period;

7. Adopting a prescription approach and referencing it to cultivation licenses issued under the proposed scheme would meet a number of identified Regulatory Objectives referred to in this submission and would further:

✓ ensure that all patients have a precise and adequate quantity of medication to

address their individual biological and therapeutic needs;

- ✓ ensure that all patients have a continuous supply of medication;
- ✓ provide checks and balances between prescribing and dispensing practitioners;
- ✓ provide checks and balances to ensure that medicinal cannabis is dispensed strictly to those licensed under the scheme;
- ✓ enable General Medical Practitioners and/or Medicinal Cannabis Practitioners the flexibility to prescribe at shorter intervals (14 days) at the outset of treatment (if required) in order to monitor patients with no prior exposure to cannabis and/or low tolerance levels and/or for those patients identified as vulnerable or at risk;
- ✓ ensure that the patient returns to their General Medical Practitioner or Medical Cannabis Practitioner for regular review and monitoring;
- ✓ provide a means of monitoring a patients medicinal cannabis use, general health and therapeutic outcomes;
- ✓ assist in determining the quantities of medicinal cannabis demanded and/or in supply through out Victoria during any one period in time, thereby assisting regulators in the issue of commercial cultivation licenses;
- ✓ assists in ascertaining the quantities of medicinal cannabis demanded and/or in supply through out Victoria during any one period in time, enabling regulators in examining the performance of the scheme with a view to improving the same;
- ✓ assist regulators in examining prescription data associated to quantities and particular strains of cannabis being supplied to patients under prescription. This data could be collated, examined and/or used for regulatory and or medical and scientific research purposes;
- ✓ provides a regulatory means of monitoring supply, use, misuse and possible diversion to the illicit market by all licensed persons and/ or entities under the scheme.

8. in many states in the USA, the total quantity of cannabis a patient may have in their possession under a cultivation license is generally limited by prescribing the total quantity of plants a patient may cultivate at any one time. The number varies from 10 to 15 plants. Scientists have expressed concern regarding these figures and have called for an allowance of up to 100 plants to ensure that patients with higher medicinal needs are not left short of medication[494];

9. it is vital that a patient have access to sufficient quantities of medication to alleviate their

pain and suffering. Anything short thereof, would be ethically questionable and considered inconsistent with existing Human Rights laws;

10. this submission does not support the arbitrary allocation of a quantity of plants that a patient may be permitted to grow under cultivation license. If a patient is to have sufficient medication to address their specific individuals medical needs, the number of flowering plants and the yield of cannabis therefrom, must be sufficient to ensure that it will meet a patient's maximum prescribed total daily dose. To ensure such an outcome a mathematical approach is required;

11. this submission advocates the adoption of a mathematical formula similar to that employed under the Canadian medicinal cannabis program:

    - Under this formula a patient is permitted:

        - to grow one outdoor crop using a 12 month calculation; or
        - up to three indoor crops using a 12 month calculation; or
        - to grow one out door crop using a 6 month calculation and up to two indoor crops using a 6 month calculation (but not simultaneously);
        - to store a quantity of cannabis calculated from the crop yield referred to as a ''storage quota;''

    - The total quantity of plants permitted to be cultivated and stored by a patient is determined by reference to:

        - the patients Maximum Total Daily Dose ("MTDD") of medicinal cannabis;
        - the medication period required;
        - a deemed yield per plant (30 grams per plant indoor and 250 grams per plant for outdoor cultivation);
        - the growing cycle(s) and if cultivation is indoors, outdoors or in combination. (i.e. one up to two or three);

    - There are three equations depending on whether cultivation is:

        - entirely indoors (up to 3 crops) using a 12 month calculation period;

        - entirely outdoors (1 crop) using a 12 month calculation period;

        - a combination of indoor cultivation (up to 2 crops) over 6 months) and outdoor cultivation (1 crop) over a 6 month period.

12. It is believed that the Canadian Health calculations for outdoor cultivation have recognised the variability and hazards associated with outdoor agriculture. Provision has been made in this formula to allow for unpredictable growing conditions and seasonal differences to allow a patient to cultivate a sufficient quantity of plants that would yield a quantity of cannabis sufficient to cover a patients medicinal needs for 12 months in advance in order to compensate for the possibility of the following years cultivation failing to produce cannabis to address a patients medicinal requirements.[495] This submission supports such a proposal for Victoria, given the propensity to drought

and harsh climatic conditions (i.e. bush fires) experienced across the state that could destroy crops and/or leave a patient without medications for 12 months;

13. Where a patient elects to cultivate and harvest their entire medicinal cannabis needs outdoors, and the season has yielded an additional 12 months of medication to compensate for a possible poor agricultural season the following year, the issue of a Medicinal Cannabis Card in the subsequent year would issue a card with a code denoting that the PPL was inactive for the duration of the cards renewal over that 12 month period. Reference to the PPL in this manner, would indicate that the quantity of cannabis in the patients possession was a lawful quantity under a permitted storage quota issued under a valid license 12 months previously.

14. Represented mathematically the permitted number of plants a patient could cultivate over a grow cycle is expressed as follows:

1. <u>WHERE CULTIVATION IS ENTIRELY INDOORS</u>

ENTIRELY INDOORS

Up to 3 crop cycles or grows all to be cultivated indoors

Represented mathematically as:

$P = [(G \times 365) / (GP \times 3\ C)] \times 1.2$

<u>Where</u>:

P = total plants allowed to cultivate by having reference to:

G = Maximum Total Daily Dose ("MTDD") of Medicinal Cannabis;

GP = 30 grams produced per plant:

C = the number(s) of the grow cycles permitted

<u>Where an expected crop yield is represented mathematically as</u>:

$Y = P \times GP$

<u>The permitted storage quota is represented mathematically as</u>

$S = Y \times 1.5$

EXAMPLE

Plants cultivated INDOORS for a patient on a Maximum Total Daily Dose of 5 grams a day:

Total Plants that may be Cultivated INDOORS:

P = G (5gm) x 365 = 1,825 gram / 30 gram x 3 crop grow x 1825 gram /90 x 1.2 = 24.

P = 24 plants for one of up to three indoor grow cycles

Expected Yield from an INDOOR Crop

Y = 24 plants x 30gm = 720 grams.

Permitted Storage Quota from an INDOOR Crop

S=Y x 1.5

S= 720gm x 1.5 = 1,080 grams

S= 1,080 gram per one of three permitted indoor crop/grow's a year.

At a MTDD of 5 grams a patient cultivating up to 24 plants in one of three permitted annual indoor grow cycles would be storing between 720 and 1,080 grams or enough for 143 to 216 days of cannabis medication.

2. WHRE CULTIVATION IS ENTIRELY OUTDOORS

ENTIRELY OUTDOORS

One crop grown outdoors

Represented mathematically as:

P = [(G x 365) / (GP x 1 C)] x 1.3

Where:

P = total plants allowed to cultivate by having reference to:

G = Maximum Total Daily Dose of Medicinal Cannabis ("MTDD");

GP = 250 grams produced per plant:

C = the number(s) of the grow cycles permitted

Where an expected crop yield is represented mathematically as:

Y = P x GP

The permitted storage quota is represented mathematically as

S= Y x 1.5

EXAMPLE:

Plants cultivated OUTDOORS for a patients on a Maximum Total Daily Dose of 5 grams a day

Total Plants that may be Cultivated OUTDOORS:

P =G (5gm) x 365 = 1,825 grams / 250 grams (GP indoor) x 1 crop grow x 1.3 = 10 plants

P = 10 plants to be cultivated in one outdoor crop/grow.

Expected Yield from One OUTDOOR Crop

Y = 10 x 250gm = 2,500 grams

Permitted Storage Quota from one OUTDOOR Crop

S=2,500 x 1.5

S = 3,750 grams per one outdoor crop/grow.

At a MTDD of 5 grams a patient cultivating up to 10 plants in one annual out door grow cycle would be permitted to store between 2,500 grams and 3,750 grams or enough for 500 to 750 days of cannabis medicine.

3. WHERE CULTIVATION IS A COMBINATION OF INDOORS & OUTDOORS

. divided into two consecutive 6 month periods allowing up to 2 indoor cultivations and one outdoor cultivation, but not simultaneously.

INDOOR PART OF THE EQUATION

A **Total Plants that may be Cultivated INDOORS**:

Up to 2 crop cycles or grows both to cultivated indoors

Represented mathematically as:

$P = [(G \times 182.5) / (GP \times 2C)] \times 1.2$

Where:

P = total plants allowed to cultivate by having reference to:

G = Maximum Total Daily Dose of Medicinal Cannabis;

GP = 30 grams produced per plant:

C = the number(s) of the grow cycles permitted

Expected Yield from an INDOOR Crop

$Y = P \times GP$

-AND-

OUTDOORS PART OF THE EQUATION

B. **Total Plants that may be Cultivated OUTDOORS:**

One crop grown outdoors

Represented mathematically as:

$P = [(G \times 182.5) / (GP \times 1C)] \times 1.3$

Where:

P = total plants allowed to cultivate by having reference to:

G = Maximum Total Daily Dose of Medicinal Cannabis;

GP = 250 grams produced per plant:

C = the number(s) of the grow cycles permitted

Expected Yield from an OUTDOOR Crop

Y = P x GP

-AND-

STORAGE QOUTA FOR INDOORS & OUTDOORS

C. **Permitted Storage Quota's for both the Indoor & Outdoor grows:**

Represented mathematically as:

S= P x GP X 1.5

Where:

P = is the total number of plants derived from the outdoor calculation x by the GP for outdoor cultivation x 1.5.

EXAMPLE:

Plants cultivated indoors and outdoors for a patients on a Maximum Total Daily Dose of 5 grams a day.

A. **Total plants cultivated INDOORS**

P = [(G x 182.5) / (GP x 2C)] x 1.2

P = 5 grams x 182.5 = 912.5 grams
912.5 / 30gm x 2 or
912.5 / 60 grams = 15.2083333 x 1.2 = 18.25

P = 19 plants.

Expected Yield from an INDOOR Crop

Y = 19 plants x 30gram = 570 grams

B **Total Plants that may be Cultivate OUTDOORS**:

P = [(G x 182.5) / (GP x 1C)] x 1.3

P= 5 grams x 182.5 = 912.5 grams
912.5 / 250gm x 1 =3.65
3.65 x 1.3 = 4.745

P = 5 plants

Expected Yield from an OUTDOOR Crop

Y = 5 plants x 250gm = 1,250 grams

C. Total Storage Quota Permitted

For the INDOOR crop yield:

5 grams x 250 grams x 1.5 = 1,875 grams

For the OUTDOOR crop yield:

5 grams x 250 grams x 1.5 = 1,875 grams

15. The Canadian calculation appears to: employ a low deemed yield of 30 grams for plants cultivated indoors and 250 grams for plants cultivated outdoor. Low plant yields are generally associated with low lighting levels and unsophisticated growing techniques;

16. Adopting a low yielding figure under the calculation would ensure that:

- patient's who are not adept cultivators would still produce a yield that would cover their specific medication requirements; and/or

- patients could grow under low lighting levels keeping electricity costs manageable.

An adjustment in the form of a multiple of 1.5 to the storage allowance would appear to compensate for the low deeming figure, equating the resultant yield to approximate a more realistic total yield from the number of plants cultivated.

17. This submission suggests that the calculations could be used as a basis for adoption with the following suggested modifications:

    a. that reference to the permitted number of plants be a reference to ''flowering plants";
    b. female plants deliver flowers which are required for medicinal purposes;
    c. the sex of a plant is not always readily discernable prior to cultivation and some cultivators find that they have grown more male plants than females;
    d. that in turn will affect quantity yielded from a crop and the ability to satisfy a patient's Maximum Total Daily Dose of medication requirements;
    e. although feminized seeds are available to cultivators, they are not favoured within where a crop is being cultivated for medicinal purposes;
    f. references to the permitted quantity of ''plants'' that a patient might be permitted to cultivate at any one time, should therefore be a reference to ''flowering plants;''
    g. an allowance for the cultivation of trailing seedlings and/or clones or propagated juvenile plants to allow for a continuous supply of medicine and growing operation extending over consecutive permissible grow cycles and/or to compensate for culling of male plants and natural plant attrition rates. A ratio of 2 (trailing plants):1 (plant) be formulated to allow for 50% cull rate of male plants and general plant attrition has been suggested;

18. Any unexpected yield over and above a patients calculated permitted storage quota must be destroyed under the Canadian medicinal cannabis program[496]. Current reforms for a ''Harmonized'' Canadian Medicinal Cannabis Scheme proposed by Medicinal Cannabis Patients Alliance of Canada Inc. advocates that cultivators be permitted to sell such excess to Medicinal Cannabis Dispensaries, after the same has been subjected to rigorous laboratory analysis[497]. This submission supports this proposal together with the ability to donate such excess crop yield over a permitted storage quota to a Compassion Club or Co-operatives. **[**"Cultivation: Personal Production" and "Designated Production and Third Party Cannabis Producers" in this submission.]

19. This submission supports the proposed sale or donation of any unexpected cannabis crop yield excess over a patients permitted storage quota, rather than destruction as:

- it may over come having to comply with provisions in Commonwealth legislation,

such as S.19 of the Narcotic Drugs Act 1967 (Cth) regarding destruction of cannabis;

- it allows the financially disadvantaged patient holding a personal cultivation license to offset the capital, running and possible storage costs associated with growing their medications; [See: "Cultivation: Designated Production and Third Party Cannabis Producers" in this submission.]

- It promotes greater interest in producing higher quality cannabis by personal cultivators;

- it could offer speciality strains to Medicinal Cannabis Dispensaries and/or Compassion Clubs that are not otherwise produced and / or available;

- donations of excess cannabis to Compassion Clubs / Co-Operatives could assist the financially disadvantaged who cannot hold a personal cultivation license and/or cannot afford cannabis prices offered through retail Medicinal Cannabis Dispensaries.

20. Accordingly, under the proposals advocated:

20.1. a patient, parent, guardian or carer under a PPL or DPL (A) would be permitted to cultivate:

a. up to 3 indoor crops where they elected to cultivate all crops indoors; or

b. one crop where they elected to cultivate entirely by this means; or

c. up to 2 indoor crops and 1 outdoor grow, but not simultaneously;

as stipulated as a permitted storage quota, and calculated under the terms of their licence.

20.2 a patient, parent or guardian may personally cultivate under a PPL:

- a precise quantity of seeds, clones or propagated juvenile's and flowering plants to cover the patients maximum total daily medication dose and needs;

- indoors, outdoors or a combination thereof (but not simultaneously) over a 12 month period or any part thereof;

in the quantities sufficient to meet their Maximum Total Daily Dose of medicinal cannabis and as set out in the conditions of their license and;

- the quantity referred to would be determined by an equation similar to the one employed by Health Canada under the Canadian medicinal cannabis program having reference to:

  - the patients Maximum Total Daily Dose;
  - the medication period required;

- a deemed yield per plant (30 grams per flowering plant indoor and 250 grams per plant for outdoor cultivation);
- the number of growing periods;
- a percentage to allow propagated juvenile or trailing plants as well as for male/non plants and plant deaths;

20.3 a patient, parent or guardian holding a PPL under the terms of the license would be:

a. permitted to possess and store up to a specific quantity of cannabis referred to as a "permitted storage quota;" sufficient to accommodate their total daily medication needs; or

b. have it stored (or part thereof) at a Medicinal Cannabis Dispensary [See: "Cultivation: Personal Production: and "Designated Production and Third Party Cannabis Producers" in this submission] and may;

c. sell unexpected excess of a cannabis crop yield over the patients permitted storage quota (if any) to:

- a Medicinal Cannabis Dispensary; or
- donate it to a nominated Compassion Club or Co-Operative; or
- otherwise destroyed or dealt with under any regulations.

[See: "Cultivation: Designated Production and Third Party Cannabis Producers" in this submission.]

20.4 upon the issue of a DPL(A) a patient, parent, guardian or carer may engage a third party to cultivate cannabis for the benefit of the patient. The third party cultivator may be a Compassion Club or Co-operative operating under a Designated Production License or DPL (A) (appointing its own third parties that cultivate exclusively for the club) or an individual or commercial producer under a Designated Production License; [See: "Cultivation: Designated and Third Party Cannabis Producers" and "Processing and Distribution: Compassion Clubs" in this submission.]

20.5 upon issue of a DPL (A) and engaging a third party cultivator holding a valid DPL, a patient, parent, guardian, or carer may be permitted to cultivate:

a. a specified number of seeds, clones, propagated juvenile and flowering plants to cover the patients maximum total daily medication dose and needs;

b. crops cultivated indoors, outdoors or a combination thereof (but not simultaneously) over a 12 month period or any part thereof;

in the quantities sufficient to meet their Maximum Total Daily Dose of medicinal cannabis and as set out in the conditions of their license and;

- the quantity referred to would be determined by an equation similar to the one employed by Health Canada under the Canadian medicinal cannabis program having reference to:
- the patients Maximum Total Daily Dose;

- the medication period required;
- a deemed yield per flowering plant (30 grams per flowering plant indoor and 250 grams per flowering plant for outdoor cultivation);
- the number of growing periods;
- a percentage to allow propagated juvenile or trailing plants as well as for male/non flowering plants and plant deaths;

c. where cultivation occurs via a Compassion Club or Co-Operative with a licensed Medicinal Cannabis Dispensary, the patient may:

- receive a variety of strains of cannabis under prescription, pooled from a variety of crops grown on behalf of members; but

- may only receive a quantity of cannabis dispensed under the patients prescription up to the patients permitted storage quota as calculated and specified under the terms of the DPL (A); or

d. where the crop is cultivated by an individual or a commercial producer, the patient, parent, guardian or carer may:

- take delivery of the crop up to the patients permitted storage quota calculated and specified under the terms of the DPL(A); and/or

- direct that the same be stored at a Medicinal Cannabis Dispensary for safe keeping and dispensing; and/or

- direct an unexpected excess of a cannabis crop yield over the patients permitted storage quota specified under the terms of the DPL (A) to be:

  - sold to a Medicinal Cannabis Dispensary (in lieu of storage fees); or
  -
  - donated it to a nominated Compassion Club or Co-Operative; or

  - otherwise destroyed or dealt with under any regulations.

[See: "Cultivation: Designated Production Licenses and Third Party Cannabis Producers" in this submission].

20.6 a patient, parent, guardian or carer making an application for a license under a scheme proposed by this submission would specify:

(i) what licences are required (if any) by the patient in addition to an Authority to Possess License issued in the form of a Medicinal Cannabis Card; and

(ii) the percentages of their Maximum Total Daily Dose of medicinal cannabis identified in their treatment plan that is to be supplied under one or more of the license arrangements required.

CULTIVATION

Under the model favoured by this submission and with appropriate legislative amendments and co-operation between the State and Commonwealth government, the Victorian Government could issue cultivation and manufacturing licenses to the following individuals:

a. patient's requiring a Personal Production License ("PPL");

b. patient's desiring a Personal Production License and who, unable to grow cannabis themselves, require a third party to grow on their behalf under a Designated Production License ("DPL");

c. commercial cultivators to supply licensed Medicinal Cannabis Dispensaries and manufacturers of cannabis products under a Commercial Production License ("CPL").

The parties and models relevant to this discussion are:

- commercial licensed producers
- patients growing under a Personal Production License or "PPL"
- designated production licenses or "DPL" & third party producers.

COMMERICAL PRODUCTION

1. Producers of cannabis can operate solely as cultivators in a stand alone model or incorporated into other models including:

   - commercial cultivator as a stand alone operation that supplies dispensaries;
   - commercial cultivator with a dispensary operation;
   - commercial cultivator and manufacturer of cannabis goods supplying dispensaries; and
   - commercial cultivator and manufacturer, with a dispensary operation.

2. These models would require the operators to hold a combination of licenses to cultivate, supply and sell cannabis and cannabis products from the Victorian Government and a manufacturing license from the Commonwealth Government. [See: "Cultivation, Processing and Distribution" and ""Regulatory Frame Work"" in this submission].

3. The issue of Commonwealth and Victorian licenses simultaneously by the Victorian Government in the form of one license could be attended to via an agreement reached between the Commonwealth and Victorian Governments. Such an agreement could also include the delegation and or sharing of operational and regulatory responsibilities.

4. It would be envisaged that under the model favoured by this submission that commercial producers would be issued with a Commercial Production License ("CPL") to grow various cannabis strains on a large commercial scale to be determined with reference to demand generated by applications made by patients, parents, guardians and carers, for Medicinal Cannabis Cards and or various cultivation licenses issued under the scheme.

5. The quantity of plants to be grown under a CPL would be determined by the Victorian Government. Patients entering the scheme would:

   - apply for one or more authorities or licenses that would issue in the form of a Medicinal Cannabis Card with relevant license codes; and

   - patients who do not wish to cultivate their own cannabis for medicinal purposes directly under a Personal Production License or PPL, would apply on entry to the scheme, for an Authority to Possess License or APL, that would be represented in the form and issue of a Medicinal Cannabis Card; and

   - patients, parents, guardians or carers who wish to have their prescriptions for medicinal cannabis filled at a retail dispensary and have no intention to have an individual or Compassion Club to cultivate and dispense their medicinal cannabis, they would simply apply for a Medicinal Card (APL); and

   - upon application for a Medicinal Cannabis Card, the applicant would specify that the quantity of cannabis permitted by the terms of license, is to be sourced from a commercial cultivation producer or producers.

     The applicant however, would not be required to nominate a specific commercial producer or acquire cannabis under a valid prescription from such supplier that may operate a Medicinal Cannabis Dispensary. As medicinal cannabis therapy requires matching cannabinoid and terpene profiles to specific and highly individualised medical needs, it is important that patients be given the autonomy to purchase different strains of cannabis cultivated by different commercial producers and distributed through various Medicinal Cannabis Dispensaries. The nomination process is designed strictly for administrative purposes only in order to assist the Victorian Government in determining the total quantity of plants and cannabis that can be cultivated by commercial producers across the state under CPL's within a 12 month period. By requiring the annual renewal of Medicinal Cannabis Cards by patients, parents, guardians, and carers, projections for commercial cultivation under CPL's could be more easily made and assessed by the Victorian Government;

   - or may apply for an "Authority to Designate Production under License" or a DPL (A) to enable them to engage a commercial producer to directly cultivate a crop of cannabis on their behalf; [See: "Designated Production Licenses and Third Party Cannabis Producers" in this submission].

     A patient, parent, guardian or carer might seek such a license where they are unable to cultivate their own cannabis under a Personal Production License or PPL and / or are unable to access the same via a third party cultivator or by joining a Compassion Club or Co-operative. This could be particularly relevant to persons living in rural regions of Victoria. Alternatively, patients participating in scientific trials or who have a special need for a particular strain of cannabis which is not readily available, might also benefit from this arrangement. It is submitted, that a certain percentage of a commercial producers cultivation capacity be set aside to facilitate such arrangements and that such be made a condition of CPL issues and renewals. [See: "Designated Production Licenses and Third Party Cannabis Producers" in this submission.]

6. Consistent with models operating in overseas jurisdictions commercial producers holding a CPL would operate on a not for profit basis. It is submitted that regulations should stipulate that cannabis be provided at ''compassion based'' or at marginal prices above ''at cost'' pricing. A failure to establish and/or any inconsistencies in approaching compassionate pricing, has been a criticism levied at the operation of overseas models. [See: "The Cost of Cannabis" in this submission].

7. In line with overseas jurisdictions the following measures could be considered for adoption into a medicinal cannabis model.

7.1 Licenses could be issued via a competitive process[498] and selection criteria might include:[499]:

a. the suitability of location and premises, which in addition to meeting the requirements of S. 12 of the Narcotic Drugs Act 1967 (Cth)-might include such measures as operating in a locked facility away from public view with appropriate security measures such as: video surveillance, alarm/monitored alarm systems, appropriate fencing, lighting, loitering avoidance measures, secure transportation facilities;

b. the suitability of the cultivation site. With regard to outdoor cultivation, a site that is:

- removed from environmental pollutants and chemicals (i.e. heavy metals, mining locations, contaminated soils and/or land fill or
- land positioned in an agricultural zone that might be situated downwind from chemical and or pesticide spray drift used on other crops);
- not adjacent to a school, day care facility, public playground or space frequented by persons under 18 years;

c. the submission of relevant environmental assessment and soil reports associated with (b);

d. submission of a general as well as specific risk management plans concerning: cultivation, processing, laboratory testing, storage, packaging, security, occupational health and safety, product processing, sale and supply;

e. a consideration of the skill and experience of cultivators to be employed by the applicant and their knowledge associated with cannabis and cannabis cultivation;

f. whether an applicant and their staff members are deemed ''fit and proper'' persons to cultivate, manufacture, supply and/or sell cannabis;

g. a considerations of the financial stability of the applicant and the financial viability of their proposed business model and submission;

h. an examination of the level of skill and experience on the part of the applicant and their management team in operating a viable business;

i. an examination of the applicants capacity to produce an adequate and continuous supply of medicinal cannabis;

j. a consideration as to the capacity of the business model to make cannabis available at a compassionate prices;

k. an examination of the capacity of the business model to take on a specific percentage of their cultivation capacity for medical and scientific research projects; and/or

l. if operating cultivation and a dispensary operation: the ability of the business model to meet licensing requirement and conditions associated with the operation of a dispensary and its proximity and location to patient's; and/or

m. an option for discrete delivery by mail or courier direct to patients in accordance with a valid prescription.

7.2 Licenses would be renewable every 12 months.

7.3 The following conditions, obligations and restrictions might be considered appropriate for regulatory purposes:

a. the applicant holding (where relevant) valid licences for manufacture, supply and or sale of cannabis and cannabis products;

b. the sale/distribution of cannabis to be supplied exclusively and strictly to other licensed commercial producers, dispensaries or manufacturers operating under the scheme;

c. cultivation and harvest to be restricted to the production site authorised under the license;

d. storage of medicinal cannabis must be kept indoors at the site authorised under the license, until delivery to the intended recipient(s);

e. crops to be grown at the premise identified on the license[500]; in a locked facility away from public view with appropriate security measures such as: video surveillance, alarm/monitored alarm systems, appropriate fencing, lighting, loitering avoidance measures and secure transportation facilities;

f. adherence to security and tracking measures of cannabis produced to avoid theft and diversion to the illicit market i.e. RFID chipping of flowers and plant from seed to sale, to account at all times for all quantities cultivated, processed, stored, distributed and sold;[501]

g. daily reconciliation of inventory and sales;

h. batch identification in the form of registration numbers being traced through a tracking and inventory system from cultivation to laboratory and to point of sale;

i. inventory tracking to include batch identification process referred to at paragraph (f) and (h) to correspond with:

- ➢ numbered tamper proof/tamper evident sealed bags which can be traced through an inventory system from cultivation right through to point of sale; and

(ii) be clearly identified on any dispensing containers, vessels, shelf and storage locations, in which the same is housed on the cultivation premises before point of sale, for tracking, inventory and audit purposes;

j. regular inventory reconciliation statements to be lodged electronically with the relevant Victorian Government agency or department established for administering the scheme;

k. nitrogen filled tamper evident sealed bags or similar [502]to be used to keep produce fresh, free of mould, bacteria, foreign matter and secure from theft –for storage and during transit/delivery to a manufacturer or dispensary; and

l. annual auditing, together with the occasional ''on the spot audit'' of inventory, financial records and premises. Record keeping and the auditing process would also include compliance with S 23 Narcotic Drugs Act 1967 (Cth) and submission of such records /reports and returns to be provided to the Commonwealth Secretary with respect to manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;

m. mandatory reporting of discrepancies, unusual waste, destruction of crops, disappearance of inventory and suspected thefts, to a local Law Enforcement agency within 24 hours and the relevant Victorian Government agency or department established for administering the scheme within 72 hours; [503]

n. adherence to regulatory compliance matters relevant quality assurance standards, inventory checks and record keeping required by Victorian and or Commonwealth Laws or by the Victorian Government agency or department established for administering the scheme and / or Local Municipal Councils;

o. purchase of seed, seedling and clones from other licenced cultivators only and/ or the Victorian Government or other authorised sources for the purposes of the scheme; [504]

p. authorised chemical agents to be used and strictly to approved levels only;

q. pesticides are to be restricted to minimal low concentration levels and to be applied strictly and only at, the early stage of a plants growth;

r. records of all chemicals and other substances as and when applied to the plants, together with a record of their quantities to be kept in a maintained register and to be available for inspection and as part of a periodic auditing process;

s. attend to mandatory batch testing from a number of different areas of a number of flowers from a plant of a specific crop batch, undertaken through specific accredited medicinal cannabis laboratories for:

- flower appearance (rating);
- cannabinoid & terpene profile expressed as percentages of total weight;
- cannabinoid and terpene profiles expressed in mg per gram;

- absence of hairs, insects, bacteria, fungi, pesticides, chemicals, heavy metals, mould or other contaminants;
- any other contaminants.

t. copies of all laboratory results related to batch testing on cannabis crops referred to at (q) to be kept in a separate register, with a copy of such reports being provided with;

u. death of any clones, propagated juveniles or plants (with or without flowers), with their means of disposal and or destruction to be recorded in a relevant register, as well as attending to any other necessary specifications, requirements or notifications to be issued to the Victorian Government agency or department or Commonwealth Secretary under the Narcotic Drugs 1967 (Cth);

v. maintenance of an online secure electronic platform providing the following general information to be accessed by and for the benefit of patients, parents, guardians, carers, General Medical Practitioners, Medicinal Cannabis Practitioners and medical research scientists:

(i) the various strains of cannabis being cultivated by the commercial producers,
(ii) cultivation and curing processes;
(iii) a list of agricultural and horticultural substances applied to crops;
(iv) accredited laboratories used by the commercial producer for crop batch testing purposes and any details associated to their accreditation;
(v) dispensaries, Compassion Clubs and manufacturer's their cannabis is supplied to;

u. maintenance of an online secure electronic platform providing the following specific information to be accessed by and for the benefit of patients, parents, guardians, carers, General Medical Practitioners, Medicinal Cannabis Practitioners and medical research scientists:

(i) age to the plants at harvest;
(ii) age of the plants at point of packaging;
(iii) laboratory reports of all batch testing of crops and cannabis strains disclosing the information at paragraph (q);
(iv) copy of laboratory certification attesting to the servicing and accurate calibration of equipment used by laboratories employed by the commercial producer to batch test cannabis cultivated and supplied;
(v) all relevant information that assists the consumer in identifying the information at (t) with cannabis that has been supplied and distributed to other commercial producers, Compassion Clubs or dispensaries;
(vi) specific agricultural and horticultural substances and/or processes applied to the batch tested plants identified by the laboratory information referred to at

(q), that may impact the health of the plant or the consumer to be disclosed (i.e. chemicals, fertilizers, pesticides, preservatives and processes like irradiation);

(vii) how often and at what stage(s) of that particular crop batches tested was such applied (i.e. at what stage of the growth cycle of the plants);

v all information including that referred to above, is to be current, regularly updated, accurate and retained there for a designated period specified by regulations and thereafter, to be archived.

w. maintaining required registers specified by regulations under the scheme including but not limited to the following separate registers:

- Horticultural Register;
- Laboratory Register;
- Commercial Processing Register;
- Inventory Register;
- Sales and Distribution Register;
- Auditing Register;
- Substandard Product, Returns and Product Recall Register;
- Quality Assurance Standards and Compliance Register;

By way of example the following or similar information could be entered into registers:

Horticultural Register could contain the following details kept for each crop cultivated:

(i) the total number of seeds of a particular cannabis strain planted;

(ii) the total number of clones and / or propagated juveniles;

(iii) the total number of plants of a particular strain;

(iv) the number of flowers (as they appear) on a plant of a particular strain;

(v) the total number of flowering plants of a particular strain;

(vi) assign an identification number (RFID or otherwise) associated with each seed, clone, juvenile, flower and plant;

(vii) referring to the identification number assigned to each, specify if such seed, clone, propagated juvenile, flower or plant is being cultivated indoors or outdoors and its precise location on the cultivation site;

(viii) identify for whom each seed, clone, propagated juvenile or plant is being cultivated for with reference to identifying details including their license or registration number under the scheme;

(ix) date propagated and / or planted, potted, re potted and / or re planted with referenced to the seed, clone, propagated juvenile, flower or plants identification number and location on the cultivation site;

(x) Where a seed, clone, propagated juvenile, flower, flowering plant or plant, is to be moved from one position to another on the cultivation site, details for the relocation, together with the date and time of its relocation are to be recorded;

(xi) details of all natural and synthetic horticultural substances, (including water) applied to the seed, clone, propagated juvenile, flower, flowering plant or plants with specific details as to:

- date of each and every application;
- time of each and every application;
- temperature, humidity and general weather conditions (outdoors);
- temperature and humidity (indoors);
- products name, manufacturers and or distributors details, product number/batch number and best before date;
- precise quantity of i.e. mcg, mls, Ltr, ounces, grams, pounds, kilos;
- the age of the plant upon each application;
- where additional or irregular applications of product are applied, details for doing so;
- specific details of any irregularities with the appearance of the plant, signs of distress, deterioration and / or poor health ("plant health"), including but not limited to: signs of pests, disease, fungi, mould, bacteria and other biological abnormalities. All affected plants and their identification numbers and their location on the cultivation site to be entered in to the register;
- Where plants are removed from their location on the cultivation site, (prior to harvest) details are to be entered into the register of their new location on the cultivation site and if the same are to be destroyed, details of the same and cross referenced into other relevant registers. Where the plant is to be removed off the cultivation site (strictly for horticultural analysis/assistance), details must be entered into the register providing reasons, the plants

location together with details of the party who has possession and control of the same;

- specific details of action taken to address “plant health” problems referred to above;
- details of all plant deaths are to be recorded, including dates, possible causes of death, means of disposal and or destruction, as well as attending to any other necessary specifications, requirements or notifications to be issued to the Victorian Government agency or department or Commonwealth Secretary under the Narcotic Drugs 1967 (Cth);
- date of harvest of each seed, clone, propagated juvenile, flower, flowering plant or plants with reference to their identification numbers, crop plantation number, location on the cultivation site;
- weight of each seed, clone, propagated juvenile, flower, flowering plant or plants at the date of harvest, using pharmacy, industrial or similar grade calibrated and regularly serviced scales;
- date and details associated with curing, processing and storing the harvest of each seed, clone, propagated juvenile, flower, flowering plant or plants with reference to their identification numbers, crop plantation number and location on the cultivation site at each stage of processing;
- batch and or registered supply numbers on the cannabis sealed and tamper proof/tamper evident bags and packaging that each quantity of the harvested plant material and or crop is dispensed into and or any other temporary inventory vessel similarly marked, to be recorded.

A **Laboratory Register** could contain the following details kept for each crop cultivated:

(i) the details of all accredited laboratories used by the commercial producer;

(ii) copies of all laboratories accreditation certifications associated to the testing of cannabis;

(iii) copies of all laboratories annual certifications regarding the calibration and servicing of laboratory equipment used to identify and quantify the cannabinoid, terpene and other properties in the plant;

(iv) the identification number of each seed, clone, propagated juvenile, flower or plant to be tested, together with the location on the cultivation site and the date they were removed from such location for such purposes;

(v) an assigned batch number to be given by the commercial producer to the seeds, clones, propagated juveniles, flowers or plants to be tested, with such batch identification number to be provided to and quoted by the laboratory receiving such – in any and all tests, reports and or documentation issued in respect of the test subjects;

(vi) the purpose for which the seeds, clones, propagated juveniles, flowers or plants were being sent to the laboratory;

(vii) details of the laboratory to which seeds, clones, propagated juveniles flowers or plants are to be sent to;

(viii) details of and a copy of a receipt issued by the laboratory acknowledging each seed, clone propagated juvenile, flower or plant received by the laboratory, quoting the commercial producers identification number for each;

(ix) copies of all results and reports relevant to the seeds, clones, propagated juveniles, flowers or plants, including but limited to test results for the matters referred to at paragraph 7.2(q) above;

A **Sales and Distribution Register** could contain the following details kept for each crop cultivated:

(i) batch and or registered supply numbers to be clearly marked on the cannabis sealed and tamper proof/tamper evident bags and packaging;

(ii) cannabis details: strain type, cannabinoid, terpene profile and THC ratio to other cannabinoids clearly marked on each tamper proof/tamper evident bags and/or packaging together with laboratory details responsible for the determination of this data;

(iii) precise weight of the cannabis determined by pharmacy or industrial grade calibrated scales which are regularly serviced clearly marked on the tamper proof/tamper evident bag;

(iv) date the cannabis was dispensed into the sealed tamper proof/tamper evident bags and / or packages, clearly marked on the same;

(v) best before/expiry date of cannabis in the sealed tamper proof/tamper evident bags and/or packages;

(vi) dispatch details: how it was dispatched and where a third party is involved in such dispatch and delivery – all relevant receipts and or other documentation issued to or by the third party;

(vii) third party purchasers (i.e. other commercial cultivator, dispensary or compassion club details) and delivery details including who is taking possession of and responsibility for cannabis;

(viii) details of third party purchaser of cannabis including their license details and registration number for the purposes of the scheme;

(ix) details of third party purchase order including:

- purchasers details including their registration and licenses details for the purposes of the scheme;
- the strains of cannabis ordered/purchase;
- the quantity/weight of cannabis ordered/purchased of each cannabis strain;
- the identifying batch and or registered supply numbers on each tamper proof/tamper evident sealed bag and/or packaging enclosing the same;
- the date of their order;
- the total cost of their order;
- delivery address and instructions;
- invoice details.

(x) date of receipt of delivery of cannabis;

x. all registers are to be maintained and available for inspection for the purposes of audit and general inspection by those purchasing from the CML holder;

y. substandard and/or damaged cannabis with details thereof including strain, batch and registered supply numbers, date packaged, date received, purchasers details, cross references to invoices numbers issued in relation to the purchase, details (if any) related to storage, date and arrangements made for the secure return of the same to the commercial producer, together with receipt, quantity received on return of cannabis and disposal details, to be entered into the Substandard Product, Returns and Product Recall Register. This register would also hold details, data, records, notices and other information to comply with the Narcotic Drugs Act 1967 (Cth);

z. records, reports and documents relevant to quality assurance issues, compliance with regulations, audits and site inspection reports issued by the relevant Victorian Government agency or department and/or Local Municipal Councils to be held and maintained in the Quality Assurance Standards and Compliance Register.

7.4 Revocation of a CPL might occur where:

- the license holder requests the revocation;
- the license holder breaches one of the conditions referred to at paragraphs 7.3 a, b, c, d, e, k, m, p, q, r, s ,w;
- the license was obtained on the basis of false or misleading information.

7.5 Revocation of a CPL would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and
- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process.

7.6 Where a license is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return their license within 30 days of receiving the notice referred to at paragraph 7.5 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively.

7.7. Where a license holder wishes to challenge the reasons for the license revocation, the license would be forfeited at the conclusion of any review or appeal process if the outcome did not favour the license holder. It is important that patients have access to medicine and that the supply of medicinal cannabis is not unduly interrupted until all claims leading to the revocation of the license have been heard and definitively determined. Anything short of such could amount to a breach of patients fundamental Human Rights.

PERSONAL PRODUCTION

1. This element of the model favoured by this submission would require the proposed cultivator to hold a combination of licenses to cultivate, manufacture and possibly supply and or sell cannabis from the Victorian Government and a manufacturing license from the Commonwealth Government. [See: "Cultivation, Processing and Distribution", ""Regulatory Frame Work"" and "Permitted Quantity of Cannabis to be Supplied and Possessed" in this submission].

   The advantages of this proposal include but are not limited to:

   - the participation within the scheme of housebound, disabled, frail and or elderly patients;
   - the participation of patient's with chemical sensitivities, allergies and/or who wish to have control over the quality of cannabis they are to consume;[505]
   - patient with specific cannabis strain needs which commercial cultivators do not or will not provide or who run short on the supply of such strains;[506]
   - patient's who cannot be accepted by a commercial producer holding an allocated number of designated production licenses, because of the producers capacity/limitations regarding numbers of patient's and / or total plant limits;[507]
   - the financially disadvantaged who cannot afford to buy cannabis at the quantities required for therapeutic purposes at prices offered by the government and/or dispensaries.[508] In turn, this will mean that they can avoid the illicit market.

2. A large study of Canadian patient's confirmed these findings identifying that 39% of medicinal cannabis patient's sought out self production in Canada for control over quality, 36% for control over price and 41% for personal safety and to avoid the illicit market.[509]

3. As at 2013, Health Canada reported that of approximately 38,000 licenses authorising Canadian patients to possess/use medicinal cannabis issued under the Canadian scheme at that time, 28,000 of those were for personal cultivation. [510] This demonstrates the importance of and need for patients to have the ability to produce their own cannabis.

4. As witnessed in Canada, having the ability to self cultivate overcomes problems associated with a medicinal cannabis patient's inability to access supply under a scheme, when commercial producers are unable to meet patients needs and or supply patient's due to regulatory or other constraints. [511]

5. The benefits provided to patients in being able to grow their own cannabis for medicinal use are:

   - ready availability: physically convenient = **Accessibility;**
   - continuity of treatment = **Accessibility;**
   - affordability: = **Accessibility;**
   - frequency of use to alleviate suffering: = **Accessibility;**

- avoiding the illicit market = **Accessibility;** and
- knowledge of and control over conditions of growing and processing.

6. Limitations of this model have been identified as:

   - the quality of cannabis may not be of a high enough quality or consistent composition due to horticultural and agriculture considerations that only sophisticated growing operations are able to fully control;
   - cultivators may have limited expertise in refining products which can be difficult and dangerous to produce;
   - technology innovations are unlikely to be developed at domestic scale;
   - difficultly in preventing cannabis spilling over into the illicit market with it therefore being difficult to distinguish it from illegally produced flowers and products;
   - patients and carers would be subject to strict rules regarding the amount and facilities used to grow. Enforcement requires close monitoring, it is labour intensive and intrusive to patients. International experience suggests– poorly regulated grow your own increases supply to the illicit market; and
   - greater risk of home invasion, electrical fire safety risks, mould and poor air quality.

7. A patient must be able to access medicinal cannabis under any proposed scheme. Barriers which stand in the way of access must be identified and addressed.

8. The cost of medicinal cannabis can be a significant barrier to access.

9. Many chronically and terminally ill patients' suffer financial hardships. Cannabis pharmaceutical grade medicines, such as Sativex can be prohibitively expensive. Medicinal cannabis can be cultivated for less than a $0.40 a gram[512].

10. The cost of cannabis provided by the Netherlands Department of Health Bureau is currently $5 E or $8Aus. The cost of cannabis supplied by Health Canada under its medicinal cannabis scheme is $5-$12 per gram. In Israel, a month's supply of medicinal cannabis is capped at $100.[513]

11. The costs of obtaining medicinal cannabis is directly related to the quantity associated with a patient's daily dose of medicine required for symptom management and/or to address an underlying medical condition.

12. There are few studies on the quantities of cannabis being used for medicinal purposes.

13. The average daily dose of medicinal cannabis in Canada is between 18 to 28 grams a day with escalating doses up to 250 grams a day, as reported by Health Canada's records related to prescribed patient dosage under the operation of their medicinal cannabis scheme[514].

14. The right of a patient to cultivate cannabis for medicinal purposes is currently before the

Canadian Federal Court. Evidence tendered before the court in the matter of Allard –v-R,[515] suggests:

a. a financially disadvantaged patient on a daily dose of 25 grams of medicinal cannabis is required to spend between $3,750 and $7,500 per month to receive cannabis medication supplied by Health Canada at a cost of $5 to $12 per gram respectively;

b. pensioners or the financially disadvantaged patient's under the Canadian scheme are unable to purchase cannabis in sufficient quantities to manage their symptoms at the rate of $5 per gram;

c. such patient's are fore going daily necessities in order to have access to very small quantities of medicine;

d. many of these patient's are unable to purchase cannabis medicine at $5 per gram at all, for periods of time;

e. some patient's under the scheme have incurred interest bearing debts with Health Canada having purchased at these prices, with many patient's unable to repay such debts;

f. cannabis can be produced under a Personal Production License for as little as $0.38 per gram; and

g. without the ability to produce under a Personal Production License patient's are denied access to their medicine.

15. Under Health Canada's scheme licensed commercial producers were not always in a position to be a designated grower for and on behalf of a patient and/or able to keep up with demand for particular strains of cannabis. There was also no regulation with regard to ''compassionate'' pricing by such designated growers. Some offered compassionate pricing and some did not. Personal cultivation however, compensated for these weaknesses in the Canadian regulatory scheme. [516]

16. There are many reports of patients on disability support allowances, pensions and or limited incomes spending their entire allowances on purchasing poor grade street cannabis, in preference to their day to day necessities in order to manage debilitating medical conditions. Personal cultivation is a viable and essential need for the financially constrained and or disadvantaged patient, especially given that required quantities of cannabis can make this an expensive medication.

17. Without the ability to cultivate cannabis patients will be effectively denied access to cannabis medication.

18. In terms of the quality and consistency of cannabis, the ability to breed strains that provide quality and consistent compositions has been done many years in the CCV. The Commission is referred to "Cannabis: Taxonomy, Pharmacology & Therapeutic Benefits.''

19. Sophisticated cultivation has been present over the same period. Reports are not uncommonly made to the discovery of ''sophisticated growing operations'' by law enforcement officers in Victoria who dismantle the same in the course of their duties.

20. Current commercial operations in other jurisdictions are believed to have developed as a direct result of and from, the skills and techniques that have been developed and employed in the illicit cottage market. The only difference between the two today, is the size of the operations and lawful access to laboratory testing and methodology that is not currently available to cultivators in the CCV. However, greater resources and sophisticated growing operations do not guarantee quality or consistent results either. For example, in 2004 Health Canada's website stated that the THC in the cannabis they were offering averaged 10.2%. However, an independent study found that the potency of the THC was in fact only 5%. [517]

21. The problems referred to by the Commission as being identified with personal cultivation, are also witnessed in commercial operations in overseas jurisdictions[518]. They are not limited to personal cultivation. Health Canada has reported [519]the following incidents in the sophisticated growing operations of their commercial providers:

- bacteria
- pesticides
- mould

22. Of 38,000 licenses issued by Health Canada under its current scheme as at 2013, 28,000 were for self or nominee cultivation licenses[520]. Health Canada, recently removed Personal Production Licenses under the operation of its scheme for the reasons identified by the Commission: greater risk of home invasion, electrical fire safety risks, mould and poor air quality.

23. However, evidence currently before the Canadian Federal Court in the matter of Allard –v- R demonstrated that:

a. cannabis can be cultivated in small areas and spaces, indoors or out doors;

b. cannabis can be safely and securely cultivated indoors with no risk of fire, mould, odour or home invasion;

c. mould is not specifically associated with growing plants indoors and there is no scientific evidence to demonstrate that the cannabis plant is specifically associated with and/or attracts mould. Mould can be treated and can be prevented;

d. small closets, grow tents and chambers, hydroponic bloom boxes with filtration, humidifiers, ventilation and secured in sealed and/or windowless rooms with installation carried out by certified tradesmen in compliance with municipal by laws, are commonly employed by those holding Personal Production Licenses;

e. the risks identified were based on examples taken from illegal growing operations and were not based on patient's holding Personal Production Licenses;

f. patient's involved in personal cultivation operations were highly diligent and concerned with risks associated with their own homes, health and living spaces;

g. inspection of the premises of patient's involved in personal cultivation operations by municipal councils showed high levels of compliance and were clean, well maintained sites. Patient's holding such licences went to great lengths to ensure

their premises were safe, secure and free of the associated risks to guarantee the quality of the medicine they were producing;

.

h. the degree of care and attention provided to cultivation by patients involved in personal cultivation was equal to or much higher than those customarily associated with large scale standardized commercial growing operations;[521]

i. patient's attending to their own well -being in this way, removes the direct risk to public health and safety;

j. the risks identified with growing cannabis indoors or outdoors was no greater than risks associated with any other common household activity;

k. growing cannabis indoors, in a collective garden, residential or non residential setting, can be and is being done safely, discreetly, securely and free of the suggested risks; and

l. in terms of its ''danger'', there are more dangerous herbs and plants that people are permitted to currently grow, without regulation.

24. Further, there were **no** records held by Health Canada or evidence of the following associated with the 28,000 Personal Production Licenses under their medicinal cannabis scheme:

- harm from fertilizers, pesticides or use of other chemicals;
- Illness associated with growing conditions and/or the cannabis produced by such operations;
- fires;
- theft of cannabis or license holders being the victims of theft or home invasions; or
- diversion to the recreational market and /or convictions of any license holders associated with such.[522]

25. It should be emphasised that of the 28,000 Personal Production Licenses issued by Health Canada, there were no reports of illness associated with home grown cannabis. This is so, despite the absence of a mandatory requirement to subject the cannabis they produced to laboratory testing.[523]

This is not surprising and reflects the position in the Netherlands. Prior to the introduction of the medicinal cannabis scheme currently operated by the Netherlands Department of Health Bureau, an estimated 14,000 medicinal cannabis users were engaging in consuming cannabis in coffee shops under the governments non enforcement policy. With the introduction of their medicinal cannabis system approximately 12 years ago, there were 600 registered and authorised participants under their medicinal cannabis scheme. Today they have1,200 authorized participants. There is however, no evidence of illness or any adverse health effects reported to or held by the Netherlands Depart of Health Bureau associated with cannabis produced via personal

cultivation and dispensed to over 13,000 patient's though coffee shops over the past 12 years.[524]

26. Technological developments were arguably fostered by, and from, the illicit market, involving small growers. This is certainly true with regard to the horticultural development of cannabis strains of which there are reportedly over 2,500 today[525].

27. An educational program for personal cultivators to encourage horticultural best practices and foster interest in cultivation generally under a proposed medicinal cannabis scheme, would add to and continue to inspire technical innovation in the commercial sector. The lack of such programs associated with medicinal cannabis schemes in overseas jurisdictions has been criticised.[526]

28. An educational program for patient's holding personal cultivation licenses as part of a medicinal cannabis scheme would also avoid a number of the problems that are allegedly associated with such operations. Such a program could provide information and education on:

    a. how to make different cannabis products;

    b. different types of grow operations: i.e. indoor –v- outdoor;

    c. indoor growing: using various safe installation models, addressing air quality, ventilation, lighting, water, nutrition, pest control, occupational health and safety issues, security, and how to obtain necessary municipal government permits to comply with local by laws; and

    d. regulatory compliance.

29. Save and with the exception of extraction methods involving butane, Co (2) or Hexane, (which are rare in Australia and could be easily regulated in any event), producing cannabis products is a very easy and safe undertaking that has been successfully done for many years both within the CCV and overseas. Hundreds of thousands of patient's having had access to information to engage in this process, have successfully made their own cannabis medicines without incident, both here and overseas[527]. [See: "Forms, Applications and Dosing of Cannabis "in this submission.]

30. Whilst patient's and carers might be subject to strict rules as to the quantities they would be able to possess at any one time, any ''rules'' in relation to cultivation facilities would be in accordance with existing municipal bylaws and therefore should not be unnecessarily ''intrusive'' or arduous for patient's to meet.

31. In terms of monitoring personal cultivation operations, inspections would be carried out by local municipal councils. Non compliance matters of a small nature could be met in the customary fashion handled for breaches of municipal council by laws. Larger regulatory non compliance breaches could be regulated to require mandatory reporting to the Victorian Government and state law enforcement agencies. This approach should go a long way to avoiding diversion to the illicit market and appears to be working very well in jurisdictions such as Canada. Even so, there is questionable evidence to support the suggestions that self grow operations under medicinal cannabis schemes in operation in overseas jurisdictions result in diversion to illicit markets. In fact, such allegations were successfully challenged recently in Allard-v R, where Health Canada was found to have:

- no records or evidence of diversion to the illicit market/unauthorised users from over 28,000 authorised holders of Personal Production Licenses; and

- no evidence of prosecutions and/or convictions of any Personal Production License holder[528].

32. Whilst inspection may be labour intensive it is the current function of local municipal governments to carry them out. Moreover, such an aspect of a medicinal cannabis scheme would add to job creation and employment opportunities. Costs associated with the administration of the scheme could be funded in full or part, from revenues raised from commercial licensing associated with the operation of the scheme. On the revenues raised from medicinal cannabis schemes the Commission is referred to paragraph 4 h at "Government Control of Supply of Medicinal Cannabis" in this submission.

33. Regulatory compliance with existing health and occupational by laws, building codes and regulations is all that would be required to ensure cannabis is grown in accordance with the same and in a discreet and secure manner (i.e. by making provision for appropriate screening, locked inaccessible areas and reasonable security measures).

34. Consequently, in line with overseas jurisdictions, the following measures could be considered for adoption into a medicinal cannabis model:

    34.1 a patient, parent or guardian could make an application to the relevant Victorian Government agency or department responsible for the administration of a proposed scheme for Commonwealth and Victorian license that could issue simultaneously in the form of a Personal Production License or ""PPL"" authorising the patient to possess, use, manufacture, cultivate, possess, and possibly supply and sell cannabis;[529]

    34.2 a patient, parent or guardian would be issued with a PPL in the form of a Medicinal Cannabis Card with the code "PPL" denoting the nature of the license held. The license would be renewable every 12 months. This requirement would assist the Victorian Government in assessing the quantity of cannabis to be produced and supplied under commercial and other licenses operating over that time period;

    34.3 no fee or a nominal fee would be associated with the issue of a PPL;

    34.4 a Medicinal Cannabis Card with a PPL code would enable the holder of the card to:

        a. cultivate and harvest a specific number of seeds, clones or propagated juvenile plants ("trailing plants" for the purposes of cultivation) and flowering plants as stated under the terms of their PPL;

        b. the number of seeds and plants would be determined according to a mathematical equation (similar to the one adopted by the Canadian medicinal cannabis program) involving the patients required Maximum Total Daily Dose ("MTDD") of cannabis medicine prescribed by a General Medical Practitioner or a Medicinal Cannabis Practitioner for the purposes of the scheme; [See: "Permitted Quantity of Cannabis to be Supplied and Possessed" in this submission.]

c. possess and store a quantity of cannabis specified by the terms of their PPL's ("permitted storage quota") determined by the mathematical equation previously referred to [See: Permitted Quantity of Cannabis to be Supplied and Possessed" in this submission];

d. sell, donate, destroy or otherwise deal with any unexpected excess of a crop yield above a permitted storage quota in accordance with the terms of their PPL and regulations relevant to the scheme. A patient may elect to have their medicinal cannabis stored at a Medicinal Cannabis Dispensary in exchange for a nominal storage fee. This may be desired where a patient wishes to keep a large quantity of cannabis secure, possibly from curious teenagers. Such fees could be offset by sales of unexpected yields in excess of permitted storage quotas. [See: Permitted Quantity of Cannabis to be Supplied and Possessed" and "Designated Production and Third Party Producers" in this submission"].

34.5 A patient, parent or guardian on making an application for a PPL would provide the following information to the relevant Victorian Government agency or department:

a. the same personal details required for the issue of a Medicinal Cannabis Card; [See: "Medicinal Cannabis Cards & Licenses" in this submission] or

b. where a patient holds an existing Medicinal Cannabis Card the patients personal identification number on the card together with a copy of the card;

c. the completion of a form housed in the electronic data base established for the purposes of the scheme by a General Medical Practitioner or Medicinal Cannabis Practitioner setting out the patients Maximum Total Daily Dose ("MTDD") of cannabis medication for the purposes of determining the number of seeds, clones or propagated juveniles (''trailing plants'') and flowering plants permitted to be cultivated and harvested on the patients behalf and the storage quota from the crop yield permitted to be possessed by patient;

d. whether the patient intends to grow – indoors, outdoors or a combination over a 12 month growing period;

e. In line with the Canadian medicinal cannabis program, if the patient was growing entirely outdoors, an intention on the part of the patient as to whether they desired to cultivate for the current year and the forthcoming years medicinal requirements to over come unforeseeable adverse agricultural conditions in the following 12 month period. The patients permitted storage quota calculated under the mathematical equation would

f. what percentage of the patients MTDD of cannabis medicine is to be cultivated and harvested under a PPL and specifying how the remaining percentage is to be supplied and across what licenses i.e. by a

Compassion Club and /or Medicinal Cannabis Dispensary; [See: ‘’Quantity of Medicinal Cannabis to be Supplied and Possessed” in this submission.]

g. the location at which the crop(s) is/are to be grown; and

h. the location at which the crop yield (up to the patients permitted storage quota) is to be stored.

i. how the patient intends to deal with any unexpected excess of a crop yield over their permitted storage quota:

(i) sale to a medicinal dispensary – nominating a specific dispensary and providing details thereof;

(ii) donation to a Compassion Club –nominating a specific Compassion Club and providing details thereof;

(iii) destroy or otherwise deal with the same according to any relevant regulations;

as stipulated under the terms of the PPL.

35. It is submitted that regulatory requirements that might be appropriate to the holders of commercial licenses, in particular determinants as to whether a patient is a ‘’fit and proper person’’ to hold a personal cultivation license, should not apply to a terminal or chronically ill person holding a PPL under a compassionate scheme.

36. The following conditions could be considered appropriate for regulatory purposes:

a. compliance with conditions of the license i.e. number of seeds, clones, propagated juvenile (‘’trailing plants’’) and flowering plants in cultivation at any one time;

b. maintaining a Horticultural Register similar to that required to be kept by a commercial producer where the license holder intends to supply/sell any unexpected excess yield over storage quota to a Medicinal Cannabis Dispensary or donate the same to a Compassion Club; [See: “Cultivation: Commercial Producers” in this submission.]

c. maintaining a Sales & Distribution Register, similar to the register to be kept by a commercial producer [See: “Cultivation: Commercial Producers” in this submission] where the holder of a PPL desires to sell any unexpected crop excess over their permitted storage quota to a Medicinal Cannabis Dispensary or donate the same to a Compassion Club;

d. compliance with and permitting an inspection process to be carried out by the Local Municipal Council in the same municipality as the cultivation site or by the relevant Victorian Government agency or department responsible for administering the scheme;

Such a process would include two inspections:

(i) the first at the early stages of cultivation; and

(ii) the second at harvest for the purposes of identifying possible unexpected crop yield over permitted PPL storage quota; with

reports issuing from such an inspection noting such and:

- the date of anticipated harvest; and
- the date of anticipated delivery of any excess crop yield to a Medicinal Cannabis Dispensary or Compassion Club; together with
- such information and a copy of any certificate of compliance and /or report(s) being issued to:

    - the PPL license holder; and
    - Medicinal Cannabis Dispensary or Compassion Club that may be receiving any excess crop yield under the terms of the PPL license;

by the Local Municipal Council or relevant Victorian Government agency;

e. right of entry to a premises for the purposes of an inspection, should remain subject to the property owner or tenant providing the Municipal Council Officer with the consent to enter onto the property. It is submitted that to vest a right of entry to inspect, would be too intrusive and inconsistent with the a patients civil and human rights to lawfully cultivate a plant for medicinal purposes. Entry to a premises should be a co – operative process. A license may be reviewed of a PPL who refuses a site inspection on more than two consecutive occasions, without reasonable cause;

f. alternatively, a self regulatory system could be imposed with the patient being responsible for the notification requirements referred to, with random regulatory spot inspections taking place across license holders. This measure is consistent with many self regulatory legislative schemes currently in operation and would reduce administrative costs associated with the scheme. In such an instance, the proviso set out at paragraph (e) above would also apply;

g. the holder of the PPL would supply any excess to the third party nominated under the terms of their license and be provided with a receipt from the Medicinal Cannabis Dispensary or Compassion Club stating:

- date of delivery;
- cannabis strain(s) delivered;
- exact weight of the excess delivered with allowance for reasonable moisture loss from date of harvest;
- purchase price (if relevant);

with a copy to be forwarded to the Local Municipal Council and/ or relevant Victorian Government agency or department;

h. the holder of a PPL who does not wish to sell or donate any unexpected cannabis yield over their permitted storage quota would be required to destroy or otherwise deal with such in accordance with the Narcotic Drugs Act 1967 (Cth) (if applicable or as amended for the purposes of the medicinal cannabis scheme) and/or any other regulations provided to deal with the same;

i. where a patient elects to cultivate and harvest their entire medicinal cannabis needs outdoors, and the season has yielded an additional 12 months of medication to compensate for a possible poor agricultural season the following year, the issue of a Medicinal Cannabis Card in the subsequent year would issue a card with a code denoting that the PPL was inactive for the duration of the cards renewal over that 12 month period. Reference to the PPL in this manner, would indicate that the quantity of cannabis in the patients possession was a lawful quantity under a permitted storage quota issued under a valid license 12 months previously; [See: Quantity of Medicinal Cannabis to be Supplied and Possessed in this submission.]

37. Restrictions that might apply to the operation of a PPL might include:

- cultivation and harvest of cannabis is to be restricted to the production site authorised under the license;
- storage of medicinal cannabis must be kept indoors at the site authorised under the license;
- the holder of a PPL must not cultivate and/or harvest an indoor and outdoor crop simultaneously.

38. Obligations of a holder of a PPL might include:

- providing notice to the relevant Victorian Government agency or department(s) of :
    - change in the holders name, address, site production or storage location together with proof of the same;
    - complete destruction of a medicinal cannabis crop together with proof of the same;
    - theft of an entire medicinal cannabis crop together with proof of the same;
- reporting the complete theft and/or destruction of a medicinal cannabis crop to a local Law Enforcement Agency;
- showing proof of the license to a Law Enforcement Officer on demand;

- the holder of the license to attend to and maintain measures to ensure the medicinal cannabis and their Medicinal Cannabis Card remain secure;

- loss or theft of a Medicinal Cannabis Card would require the license holder to notify local Law Enforcement Officers within 24 hours and the relevant Victorian Government agency or department, within 72 hours.

39. Revocation of a PPL might occur where:

- the license holder requests the revocation;

- the license holder was not eligible for entry to the scheme;

- a General Medical Practitioner or Medicinal Cannabis Practitioner advises the relevant Victorian Government agency or department that there is no valid certification in operation;

- the license holder has breached one of the conditions referred to at paragraph 37 without reasonable cause;

- the license was obtained on false or misleading information;

- the photograph submitted for the purposes of the license is not an accurate representation of the card holder.

40. Revocation of a PPL would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and

- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process.

41. Where a license is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return their license/Medicinal Cannabis Card within 30 days of receiving the notice referred to at paragraph 40 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively.

42. Where a license holder wishes to challenge the reasons for the license revocation, forfeiture of the license would take place at the conclusion of any review or appeal process, where the outcome did not favour the license holder. It is important that the license holder have access to medicinal cannabis until all claims leading to the revocation of the license have been heard and definitively determined. Anything short of such could amount to a breach of a patients fundamental Human Rights.

Providing a patient with the option to grow their own cannabis is a vital component of a successful medicinal cannabis scheme. This component, together with the aforementioned suggested proposals, would meet many of the Regulatory Objectives identified in this submission.

DESIGNATED PRODUCTION & THIRD PARTY CANNABIS PRODUCERS

1. Some patients who require Personal Production Licenses may be unable to grow their own cannabis for a variety of reasons including:

    - physical or mental incapacity;
    - unsuitable growing or location sites;
    - inability to comply with regulatory standards and/or;
    - cost of establishing a small grow operation.

2. Patients faced with these circumstances should be given the authority to cultivate their own medical cannabis via a nominated third party. These licenses are referred to in overseas jurisdictions as ‘’Designated Production Licenses’’ (“DPL”).

3. All relevant licenses to cultivate, manufacture, supply and/ or sell cannabis by a third party would issue from the Victorian Government. [See: “Cultivation, Processing and Distribution”, “”Regulatory Frame work”” and “Permitted Quantity of Cannabis to be Supplied and Possessed” in this submission].

4. This submission supports the following proposals.

5. A patient, parent or guardian would make an application to the Victorian Government for a “Authority to Designate Production under a Licence” or “DPL (A)”.

6. The nature of a DPL(A) would bestow upon the applicant, the authority to lawfully engage and instruct a third party to cultivate cannabis for and on their behalf.

7. A DPL (A) would bestow legal authority upon a patient, parent or guardian to identify and engage a third party to cultivate cannabis on their behalf and to enable the patient to take possession and/or control of the crop yield up to an amount assigned under the license as a storage quota. Like a PPL, a DPL (A) provides lawful authority for the patient, parent or guardian to engage in such activities that might otherwise attract criminal prosecution for aiding/abetting cultivation, possession, manufacture and/or trafficking offences.

8. A third party cultivator engaged under a valid DPL (A) held by a patient could cultivate cannabis for that patient under a Designated Production License or DPL. This license would bestow the same lawful authority enjoyed by the patient, upon the third party cultivator. Consequently, a third party cultivator could lawfully engage in the activities previously referred to that might otherwise attract criminal prosecution.

9. A parent, patient, guardian or carer would be issued with a DPL(A) in the form of a Medicinal Cannabis Card holding the appropriate license code.

10. A DPL(A) would be valid for 12 months.

11. The number of designated flowering plants that a third party cultivator is permitted to harvest for a patient holding a DPL (A) and the permitted storage quota of a crop which can be possessed from the crop yield, would be determined by a mathematical calculation with reference to the patients Maximum Total Daily Dose of medication set out in the patients treatment plan. This would ensure that a patient has sufficient

cannabis to meet their specific medicinal need; [See: "Permitted Quantity of Cannabis to be Supplied and Possessed" in this submission.]

12. Where a Medicinal Cannabis Card has been issued with the code "DPL (A)", the patient, parent or guardian could then proceed to engage, authorise and instruct, a third party to grow cannabis for and on their behalf and deliver the resulting yield in accordance with the patients, parents or guardians written instructions, which are set out as conditions of the patients DPL(A) license.

13. A patient holding a DPL (A) could then proceed to lawfully nominate and engage:

    - an individual;
    - Compassion Club; or
    - commercial producer; or
    - a combination thereof

    to grow cannabis on their behalf and to take possession and/or control of a crop yield up to patients permitted storage quota identified under the terms of the DPL(A) license.

14. a patient, parent or guardian on making such an application for an DPL(A) would attend to and or provide the following information to the relevant Victorian Government agency or department(s) administering the scheme:

    a. the same personal details required for the issue of a Medicinal Cannabis Card; [See: "Medicinal Cannabis Cards & Licenses" in this submission.] or

    b. where a patient holds an existing Medicinal Cannabis Card, the patients personal identification number on the card together with a copy of the card;

    c. have a registered and/or licensed General Medical Practitioner or Medicinal Cannabis Practitioner under the scheme, attend to completing and lodging electronically:

        - a ''certification'' stating (amongst other matters) that the patient is eligible to use cannabis for medicinal purposes in accordance with the provisions of the scheme; (See: "Authorising and Prescribing Medicinal Cannabis" and "Medicinal Cannabis Clinics" in this submission.] and

        - the patients required Maximum Total Daily Dose ("MTDD") of cannabis medication set out in a patients treatment plan for the purposes of determining the number of seed, clones or propagated juveniles (''trailing plants") and flowering plants permitted to be cultivated and harvested on the patients behalf;

    d. details of the third party cultivator, together with any relevant license or registration numbers held by the party under the scheme;

    e. whether flowering plants are to be cultivated: indoors, outdoors or in combination (but not simultaneously;

f. what percentage of the patients Maximum Total Daily Dose or MTDD of cannabis medicine is to be cultivated under a DPL (A) and DPL and how the remaining percentage (if any) is to be supplied and under what license(s), together with their license numbers and or application details;

g. the location at which a crop yield (up to the patients permitted storage quota) is to be stored by or on behalf of the patient (i.e. patients home address, a Compassion Club or other Medicinal Cannabis Dispensary);

h. how the patient or applicant of a DPL(A) intends to deal with an unexpected excess crop yield (if any) over their permitted storage quota:

(i) if by way of sale to a Medicinal Cannabis Dispensary: – nominating a specific dispensary and providing details thereof;

(ii) if by donation to a Compassion Club: –nominating a specific Compassion Club and providing details thereof;

(iii) if it is to be destroyed or otherwise dealt with according to any relevant regulations.

15. It is submitted that a patient or holder of a DPL(A) may wish to store their medicinal cannabis (or part thereof) by arrangement with a Medicinal Cannabis Dispensary. This may be desired where a third party residing with a patient, might otherwise access the patients medicine. This submission supports making provision for patients to sell or donate any unexpected excess cannabis over their permitted storage quotas to Medicinal Cannabis Dispensaries and or donate the same to a Compassion Club. Providing a patient with these opportunities could:

- offset any storage and or other costs associated with the arrangement;
- would offer speciality strains of cannabis to a Medicinal Cannabis Dispensary or Compassion Club that might not be commonly available; and
- would over come some of the existing legislative requirements under the Narcotic Drugs Act 1961 (Cth) associated with the destruction of cannabis.

This submission does not support the destruction of cannabis medication.

16. As with a PPL, a DPL (A) would not only bestow lawful authority upon the patient, parent or guardian to appoint a cultivator, but would assist the Victorian Government in assessing and monitoring the supply of medicinal cannabis in Victoria under the operation of the scheme. In particular, applications for DPL(A)'s would enable the Victorian Government to assess what percentage of patients applying for such a license would require cannabis to be cultivated by commercial producers and supplied via Medicinal Cannabis Dispensaries. This would enable the Victorian Government to determine the permitted number of cannabis plants commercial producers could be permitted to cultivate each year under the terms of a Commercial Production License. In short this would assist the Victorian Government to ensure that supply of cannabis in circulation meets demand without undue excess that might otherwise arise and promote

concern regarding diversion to the illicit market. The issue of a DPL (A) would also assist the Victorian Government in tracking cannabis generally for regulatory purposes.

17. Parties that would require a DPL under the proposed scheme would include:

    a. individual cultivators;
    b. commercial producers with or without a Medicinal Cannabis Dispensary operation; and
    c. Compassion Clubs/Co-Operatives.

Individual Cultivators holding a DLP

1. Individuals may apply for a DPL. An existing relationship between the patient and third party cultivator need not exist. Individuals cultivating under a DPL might include:

    - the patients carer
    - a relative,
    - friend or associate
    - persons cultivating for a Compassion Club.

2. Under the medicinal cannabis model supported by this submission, it is proposed that applicants requiring a DPL would apply to the Victorian Government and:

    - provide details of the patient/party holding a DPL(A);
    - provide details of licenses issued to the holder of a DPL(A) (if any);
    - provide details of any other DPL(s) held by the applicant and/or how many patients (up to a total of 5) the applicant is servicing;
    - provide details of all DPL(s) held at the time of application;
    - state whether flowering plants are to be cultivated and harvested: indoors, outdoors or in combination (but not simultaneously);
    - with a combination of indoor and outdoor cultivation: how many flowering plants are to be cultivated and harvested indoors and how many flowering plants are to be cultivated and harvested outdoors;
    - provide details of the location(s) of the cultivation site(s) at which the DPL(A)'s crops are to be cultivated and harvested;
    - provide an approximate date of harvest;
    - provide details at which a crop yield (up to the patients permitted storage quota) is to be stored by or on behalf of the patient up until the date of delivery and transfer in accordance with the conditions set out in the patients DPL(A); and would
    - deliver the crop yield to the patient, parent or guardian in accordance with the terms set out in the patients DPL(A);

3. Some overseas jurisdictions limit the number of patients that an individual holding a DPL may cultivate for at any one time. This submission supports DPL license holders being permitted to cultivate medicinal cannabis for a total of up to 5 patients. This would bring Victoria into line with current proposals in overseas jurisdictions.[530] This proposal is considered reasonable in view of the fact that Compassion Clubs, that rely on DPL holders to supply cannabis for the benefits of its members, will require a reasonable

supply of cannabis from a sustainable and regulated source. Compassion Clubs are regarded as an integral part of the model favoured by this submission, and are seen as vital to providing patients with access to medication.

4. Save and with the exception of Individuals operating under a DPL who cultivate for more than two patients, this submission supports the adoption of the same regulatory requirements referred to in this submission for Personal Production Licenses, advocated by this submission. For individuals cultivating for more than two patients under a DPL, a sliding scale of regulatory requirements (i.e. with respect to security and/or other measures) depending upon the number of patients and/or quantity of flowering plants that would be cultivated at one site, might be considered appropriate. It is submitted that the sliding scale of regulatory measures should be fair and reasonable and no more onerous than those applying to the operation of Personal Production Licenses, as it is essentially an extension of that model and is not in line with commercial production. More over, recognition must be given to the fact that many of these cultivators will be supplying Compassion Clubs and Co-operatives that rely on these individuals to provide a variety of cannabis strains to ensure that patient members have access to a specific cannabis medicine, that they might not otherwise be able to access.

<u>Patient, Parent or Guardian holding DPL (A) nominates a Compassion Club or Co-operative as a DPL</u>

1. Compassion Clubs or Co-operatives operating in overseas jurisdictions engage third party cultivators to grow and supply cannabis to the club or co-operative, for and on behalf of its members. This submission favours the adoption of Compassion Clubs or Co-operatives as a part of any proposed medicinal cannabis scheme. [See: "Processing and Distribution: Compassion Clubs or Co Operatives" in this submission.]

2. Under the medicinal cannabis model supported by this submission it is proposed that:

   2.1 a Compassion Club ("Club") would apply to the Victorian Government for appropriate Commonwealth and State licenses to issue in the forms of a DPL (A) for each proposed member;

   2.2 upon the issue of a DPL (A) to the club, it could proceed to appoint a third party (individual or commercial producer) to cultivate cannabis in accordance with the limits permitted by the DPL (A) held by the patient/ member;

   2.3 the Club or Co-operative upon receipt of the cannabis supplied by third party individual cultivators under valid DPL's, supply it to club members under:

   - an appropriate dispensary license issued to it by the Victorian Government agency or department administering a medicinal cannabis scheme; and
   - the clubs constitution and membership regulations;

   2.4 a patient holding a valid DPL(A) choosing to participate in a Compassion Club, would not take physical possession of a crop yield. The cannabis produced would be pooled with the cannabis of other members and the patient would be offered access to a variety of strains of cannabis to be dispensed in accordance

with a valid prescription, up to the limit specified under the terms of the patients APL/Medicinal Cannabis Card and/or other licenses; [See: Medicinal Cannabis Cards & Licenses and "Quantity of Cannabis to be Supplied and Possessed" in this submission.]

2.5 as a Compassion Club is not directly engaged in the cultivation process and does not operate or control a cultivation operation or site, that the limitations operating in regard to those holding DPLs (cultivation of up to 5 patients) would not be appropriate or necessary and should not apply to Compassion Clubs;

2.6 a Compassion Club/Co-operative on making such an application for an DPL (A) associated with a member could provide the relevant Victorian Government agency or department(s) with:

- details of the club: address, contact details;
- where incorporated: the company details;
- registration and licensing numbers issued to the club for the purposes of the scheme;
- members details including their DPL(A)/Medicinal Cannabis Card number and a copy thereof;
- details of the proposed third party cultivator to be appointed by the club together with DPL license or registration numbers held by such a party under the scheme (if any);
- whether flowering plants are to be cultivated and harvested: indoors, outdoors or in combination (but not simultaneously) by the third party cultivator;
- with a combination of indoor and outdoor cultivation: how many flowering plants are to be cultivated and harvested indoors and how many flowering plants are to be cultivated and harvested outdoors (if known);
- provide details of the location(s) of the cultivation site(s) at which the DPL(A)'s crops are to be cultivated and harvested;
- provide an approximate date of harvest;
- provide an approximated date of delivery of the harvest;
- provide location details at which a crop yield (up to the patients permitted storage quota) is to be stored;

2.7 a Compassion Club or Co-operative would engage individuals or commercial producers to grow cannabis for club members holding a valid DLP (A). However, a Compassion Club could not direct a third party to cultivate and could not take possession of cannabis in excess of the storage quotas set out under the terms of a patient/new members DPL (A), unless and until, the Compassion Club attended to any necessary regulatory requirements to deal with any unexpected excess cannabis yielded above a DPL (A) holders permitted storage quota;

2.8 the total quantity of cannabis in the possession of a Compassion Club at any one time would represent:

- the total permitted storage quota of its membership base; and

- any unexpected excess cannabis yielded over the permitted storage quotas of such members; and
- any unexpected excess cannabis yielded over the permitted storage quotas donated to the club; and
- any cannabis acquired from a commercial producer for dispensing and/or the manufacturing of cannabis products for the benefit of members.

2.9 a patient, parent or guardian holding an a valid Medicinal Cannabis Card, with APL and DPL (A) licensing codes thereon and who are members of a Compassion Club could:

a. have a quantity of cannabis up to the total of their permitted storage quota dispensed by the Compassion Club under prescription; and

b. the percentage dispensed by the Compassion Club under prescription to a patient would be no more than the percentage of the patients Maximum Total Daily Dose of medicinal cannabis set out under the terms of all licenses held, over the prescribed period;

<u>Patient, Parent or Guardian holding a DPL (A) nominates a Commercial Producer with Dispensary as DLP</u>

1. Under the medicinal cannabis model supported by this submission it is proposed that:

1.1 a patient, parent or guardian who does not wish to:

- grow cannabis directly under a Personal Production License; or
- have an individual grow cannabis on their behalf; or
- join a Compassion Club and have cannabis cultivated by a third party DPL;

would by making an application to the relevant Victorian Government agency or department(s) for a Medicinal Cannabis Card for an APL, by stating their intention to obtain their cannabis via a commercial producer. A patient that chooses to have their medicinal cannabis supplied under prescriptions via a Medicinal Cannabis Dispensary would in effect be sourcing medicinal cannabis that is supplied to the dispensary from commercial producers;

1.2 in applying for a Medicinal Cannabis Card, patient's stipulations on how they intend to have their medicinal cannabis supplied, would assist the Victorian Government with ascertaining the quantity of cannabis that could be cultivated under commercial production licenses;

1.3 provision should be made to engage a commercial producer directly under a DPL to cultivate cannabis under a DPL(A) license to guarantee direct access to particular strains of medicinal cannabis under the scheme:

- where the patients, parents or guardians are unable to secure the services of an individual holding a DPL or have access to a Compassion Club to arrange for a third party cultivator;

- to aid scientists seeking specific strains of cannabis for medical research purposes;

Patients that live in regional or remote areas may experience the difficulty referred to. Accordingly, this submission supports the proposal that commercial producers be required to dedicate a percentage of their total cultivation capacity towards the production of cannabis as a DPL producer for such parties and that such be made a condition associated with the issue and/or renewal of a Commercial Production License or CPL.

1.4 The relevant Victorian Government agency or department responsible for administering the scheme could:

1. stipulate what percentage of the CPL holders cultivation capacity is to be allocated to this purpose; and

2. at the time of an application made for a DPL (A) by the patient, parent or guardian:

    a. issue a DPL's in the name of the CPL authorising cultivation up to number of permitted flowering plants and storage quota under the patient/ applicants DPL (A);

    b) notify the CPL of the issue of a DPL together with the DPL (A)'s details;

    c) proceed to issue the DPL (A) cross referencing the CPL/DPLs details with the applicant/ patient/parent/ guardians; and

    d) continue to issue DPL's relevant to the particular commercial producer until such time as the cultivation capacity for DPL's under the terms of the commercial producers license is reached.

1.5 Under such a proposal where a patient, parent or guardian holding a valid DPL (A), nominates a commercial producer holding a DPL to cultivate a cannabis crop for the patient, the crop yield up to the patient/guardians permitted storage quota could:

a. be securely delivered to the patient, parent or guardian by the commercial producer holding a DPL in accordance with the terms under the DPL(A); or

b. be stored at a Medicinal Cannabis Dispensary location operated by the commercial producer for and on behalf of the patient, parent or guardian holding a DPL (A) or at a retail Medicinal Cannabis Dispensary as specified in the terms of the DPL (A);

c. any unexpected excess cannabis yield over the patient, parent or guardian's total storage quota could be sold to the commercial producer or

donated in lieu of nominal storage fees, if and where a patient elects to store cannabis at a medicinal dispensary operated by the commercial producer; and

d. the patient, parent or guardian holding a DPL (A) who elects to store their yield at a dispensary operated by the commercial producer responsible for cultivating their cannabis would:

(i) have a quantity of cannabis up to the total of their permitted storage quota dispensed under prescription; and

(ii) the percentage dispensed under prescription to a patient would be no more than the percentage of the patients Maximum Total Daily Dose of medicinal cannabis set out under the terms of all licenses held over the prescribed period;

DPL (A) and DPL Proposed Regulatory Matters

1. This submission also supports the following regulatory proposals, obligations and restrictions to govern the responsibilities between a patient, parent or guardian holding a valid DPL (A) and a third party cultivator holding a DPL:

1.1 that all plants remain the property of the patient, parent, guardian or Compassion Club;

1.2 cultivation and harvest of cannabis is to be restricted to the production site authorised under the license;

1.3 storage of medicinal cannabis must be kept indoors at the site authorised under the license, until delivery to the intended recipient(s);

1.4 the holder of a DPL must not cultivate and/or harvest an indoor and outdoor crop simultaneously;

1.5 a nominal fee for cultivation to be rendered to a patient, parent or guardian by an individual holding a DPL, to cover the reasonable costs associated with cultivation and harvest;

1.6 no fees for cultivation and harvest are to be rendered to a patient, parent or guardian holding a valid DPL (A) who engages a commercial producer under a DPL;

1.7 no cultivation or storage fees are to be rendered to patients, parents or guardians holding a valid DPL (A) and who are members of a Compassion Club or Co-operative;

1.8 nominal storage fees (if and where applicable) to patients, parents and guardians to have cultivated cannabis stored at a Medicinal Cannabis Dispensary;

1.9 any regulatory requirements associated with dealing with any excess over permitted patient/guardian storage quotas is the responsibility of the DPL license holder;

1.10 reference to quality assurance standards are to be adhered to by the holder of a DPL license in regard to:

(i) whether pesticides and similar products are to be used and if so, when they are to be applied during growing stages; and

(ii) cultivation, processing, curing and storage techniques to be used.

1.11 Compassion Clubs and commercial producers are to have any cannabis acquired from excess crop yields over patient storage limits tested with accredited medicinal cannabis laboratories before offering the same for sale. These costs are to be incurred by the club and commercial producer;

1.12 the reasonable costs associated with batch testing of a cannabis crop cultivated by an individual holding a DPL at an accredited medicinal cannabis laboratory, will be incurred by the DPL (A) holder. Where a DPL undertakes to provide such, batch testing must be carried out with an accredited medicinal cannabis laboratory;

1.10. terms and details regarding the secure delivery of crop yields together with any unexpected crop yield over the DPL (A) permitted storage quota are to be set out in the terms of a patient, parent or guardian's DPL(A) license;

1.11 inspection of crops and the cultivation site for:

- cleanliness;
- safety;
- compliance with the scale of the operation ensuring plants do not exceed the quantity agreed to be supplied to the patient under the terms of their DPL (A);
- noting possible excess yield of crop over permitted DPL (A) storage quota;
- health of plants;
- integrity of the property/growing facility;
- air quality;
- evidence of mould, mildew or fungi.

to be carried out by a Compassion Club and alternatively, for and on behalf of the patient, parent or guardian (DPL (A) holder) by the Local Municipal Council in the same municipality as the cultivation site or by the Victorian Government agency or relevant department responsible for administering the scheme;

1.12. two inspections could take place:

- the first at the early stages of cultivation; and
- the second at harvest for the purposes of identifying possible unexpected crop yield over permitted DPL (A) storage quota; with

reports issuing from such an inspection noting such and:

- the date of anticipated harvest; and
- any relevant details, together with a copy of any certificate of compliance and /or report(s) being issued to:

    - the DPL license holder and
    - patient, parent, guardian; and/or
    - Compassion Club holding a valid DPL (A)

by the Local Municipal Council or relevant Victorian Government agency;

1.13 a failure to comply with standards, especially regarding the health of plants and presence of mould, mildew and or fungi and insurance policy requirements, would enable the patient, parent or guardian (DPL (A) holder) to terminate the agreement with the DPL license holder, notice of which would be served on all relevant parties including the Victorian Government;

1.14 right of entry to a premises for the purposes of an inspection, should remain subject to the property owner or tenant providing the Municipal Council Officer with the consent to enter onto the property. It is submitted that to vest a right of entry to inspect, would be too intrusive and inconsistent with the a patients civil and human rights to lawfully cultivate a plant for medicinal purposes. Entry to a premises should be a co – operative process. A license may be reviewed of a DPL who refuses a site inspection on more than two consecutive occasions, without reasonable cause;

1.15 alternatively, a self regulatory system could be imposed with DPL holder being responsible for the notification requirements stipulated with random regulatory spot inspections taking place across license holders. This measure is consistent with many self regulatory legislative schemes currently in operation and would reduce administrative costs associated with the scheme. In such an instance, the proviso set out at paragraph 1.14 above would also apply;

1.16 notification to be made by the DPL license holder to:

- the relevant Victorian Government agency or department; and
- the patient, parent, guardian and / or Compassion Club to which they belong;

of the following:

- date upon which the crop and/or any unexpected excess of the crop yield over the permitted DPL (A) storage quota is ready for delivery;
- cannabis strain(s)
- recipients details

Upon delivery the following would be provide a receipt setting out:

- recipients details including any relevant licenses or registration details for the purposes of the scheme;
- date of harvest and delivery;
- medicinal cannabis strains delivered;
- exact weight of the quantity of medicinal cannabis delivered with allowance for reasonable moisture loss from the date of harvest;
- any excess crop yield over a permitted storage quota;

with a copy of the same to be forwarded to the relevant Victorian Government agency or department(s) within 7 days.

1.17 providing notice to the relevant Victorian Government agency or department(s) of :

- change in the holders name, address, site production or storage location together with proof of the same;
- complete destruction of a medicinal cannabis crop together with proof of the same;
- theft of an entire medicinal cannabis crop together with proof of the same;
- reporting the complete theft and/or destruction of a medicinal cannabis crop to a local Law Enforcement Agency;
- Loss or theft of a Medicinal Cannabis Card to be notified to local Law Enforcement Officers within 24 hours and the relevant Victorian Government agency or department, within 72 hours

1.18 showing proof of a license to a Law Enforcement Officer on demand;

1.19 the holder of the license to attend to and maintain measures to ensure the medicinal cannabis and their Medicinal Cannabis Card remain secure;

1.20 a general register in the name of each patient is to be kept by a DPL license holder which would record:

(i) the individuals details including their DPL (A) registration number and where they are a member of a Compassion Club, the details of that club together with the DPL (A) license number issued to the club in respect of the member;

(ii) the details of the DPL (A) license indicating the number of seeds, clones, propagated juvenile plants and flowering plants permitted to be cultivated and harvested under the DPL (A);

(iii) the actual number of seeds, clones, propagated juvenile plants ('trailing plants" for cultivation purposes) and flowering plants permitted to be cultivated and harvested indoors under the DPL (A); and/or

(iv) the number of seeds, clones, propagated juvenile plants ("trailing plants" for cultivation purposes) and flowering plants permitted to be cultivated and harvested out doors and/or in combination (specifying how many to be grown in each environment);

(v) each seed, clone, propagated juvenile plant ('trailing plant" for cultivation purposes) and flowering plant sown, planted, replanted, potted and or re potted to be identified with the patient, parent, guardian and/or Compassion Clubs DPL (A) number at all times and to be entered into the register, together with dates of planting, replanting, potting or re potting;

(vi) permitted storage allowance under the terms of the DPL (A);

(vii) copies and details of certificate of compliance and/ or reports from site inspection referred to at paragraph (k) above, to be kept and entered in to the register;

(viii) a copy of the certificate of compliance and or reports from site inspection referred to at paragraph 1.12 above, to be forwarded to the patient, parent, guardian and/or Compassion Club;

(ix) date, details and mail receipts of having forwarded certificates of compliance and site inspection reports to the relevant parties referred to at (viii) to be kept and recorded in the register;

(x) a copy of the notification referred to are to be kept and recorded in the register;

(xi) weight of each seed, clone, propagated juvenile, flower, flowering plant or plants at the date of harvest using pharmacy, industrial or similar grade calibrated and regularly serviced scales;

(xii) quantity, weight and other relevant details associated with any unexpected excess of cannabis yielded above the DPL(A) holders permitted storage quota (if any) to be recorded and entered into the register;

(xiii) copies, details and mail receipts of notifications referred to are to given to the relevant parties concerning unexpected yield over permitted storage quota to be kept and recorded in the register;

(xiv) date and details associated with curing, processing and storing the harvest of each seed, clone, propagated juvenile, flower, flowering plant or plants with reference to their identification numbers, crop plantation number and location on the cultivation site at each stage of processing;

(xv) batch and or registered supply numbers on the cannabis sealed and tamper proof/tamper evident bags and packaging that each quantity of the harvested plant material and or crop is dispensed into and or any other packaging, together

with any temporary inventory vessel's similarly marked, to be recorded and their location on the site premises identified;

(xvi) copies of an acknowledgement of receipt by relevant parties taking delivery of the cannabis yield and/or any excess cannabis over permitted storage quota, to be recorded and kept in the register;

1.17. a Horticultural Register to be kept and maintained by the DPL holder in respect of each crop being grown for a specific patient, parent or guardian holding a valid DPL (A) (in their own right or via a Compassion Club/Co-operative). The nature of the register would be the same or similar to that required for producers cultivating under a commercial production license or CPL; [See: "Cultivation: Commercial Producers" in this submission.]

1.18 a Sales & Distribution Register, together with any other register held by a commercial producer that may be relevant to the holder of a DPL, with any necessary modifications and allowances made in recognition of the smaller less sophisticated scales of operation carried out by individuals holding DPL's; [See: "Cultivation: Commercial Producers" in this submission.]

1.19. compliance with record keeping and auditing process regulations made in accordance with S 23 Narcotic Drugs Act 1967 (Cth) by submitting records /reports and returns (as required) to the Commonwealth Secretary regarding manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;

1.20. all DPL license holders be required to have current and relevant insurance(s) policies at all times including: public, product/agricultural/business liability insurance. Such insurance requirements where an individual DPL is growing for a patient, parent or guardian could be waived with the prior written consent of the patient, parent or guardian and noted in the terms of their DPL(A). Such a stipulation would be limited to individuals growing under a DPL for a patient who may be a parent, guardian, relative or close friend of the patient;

2. The issue of a DPL could be dependant upon or made subject to:

a. the nature and/or suitability of the location of the cultivation site;

b. the ability to process and store cannabis in a sterile, hygienic and secure manner;

c. the ability to deliver and or arrange for the secure delivery of crop yields to the patient, parent, guardian or Compassion Club and/or nominated licensed Medicinal Cannabis Dispensary;

d. the applicant and those who have access to the cultivation site, being ''fit and proper persons'' to hold such a license;

e. the existence and currency of relevant insurance policies including public and product/agricultural/business liability insurances;

f. the applicants ability to discharge regulatory compliance responsibilities under the scheme;

g. the applicants ability to comply with Local Municipal Council bylaws as well as Occupational Health and Safety regulations related to the cultivation site;

3. The renewal of a DPL could be made conditional on:

- compliance with regulations under the scheme;
- retention of current insurance policies;
- compliance with contractual arrangements with relevant parties; and
- compliance with any other special terms and conditions.

4. Revocation of a DPL might occur where:

- the license holder requests the revocation;
- the licence holder of a DPL (A) was not eligible for entry to the scheme;
- a General Medical Practitioner or Medicinal Cannabis Practitioner advises the relevant Victorian Government agency or department that there is no valid certification in operation in regard to the DPL (A);
- the license holder has breached one of the conditions referred to at paragraph 1.2 -1.4, 1.10, without reasonable cause;
- the license was obtained on false or misleading information;

5. Revocation of a DPL would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and
- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process;

6. Where a license is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return their license within 30 days of receiving the notice referred to at paragraph 5 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively;

7. Where a license holder wishes to challenge the reasons for the license revocation, forfeiture of the license would take place at the conclusion of any review or appeal process, were the outcome did not favour the license holder. It is important that patients relying on the license holder to provide medicinal cannabis, continue to have access to it. For this reason, a DPL should remain operational until all claims leading to the revocation of the license have been heard and definitively determined. Anything

short of such could deny patients access to medicine and amount to a breach of patients fundamental Human Rights. In such circumstances, regulatory provision should be made to enable transfer, cultivation and or harvest of the crops to be transferred to another DPL, so that patients relying on the medicinal cannabis crops are not denied access to their medication.

PROCESSING & DISTRIBUTION

1. With appropriate legislative amendments and co-operation between the Victorian and Commonwealth Governments, the Victorian Government could issue relevant licenses for the possession, processing, manufacture, administration, supply and sale of cannabis and cannabis products to and / or by the following individuals:

   a. Medicinal Cannabis Dispensaries;
   b. Medicinal Cannabis Clinics; and
   c. manufacturers of cannabis goods and paraphilia

2. The Commission is referred to "Cultivation, Processing and Distribution," "Regulatory Frame Work"" and "Quantity of Medicinal Cannabis to Be Supplied & Possessed Under a Proposed Scheme" in this submission.

MEDICINAL CANNABIS DISPENSARIES

1. Medicinal cannabis dispensaries ("dispensaries") operate as:

   - a stand alone operation;
   - in addition to commercial cultivation operation; and
   - as a part of a Medicinal Cannabis Clinic or Compassion Club.

2. This submission supports the adoption of Medicinal Cannabis Dispensaries. It is submitted that they platy an essential role in a medicinal cannabis scheme.

3. Medicinal Cannabis Dispensaries are vital to ensuring patients have access to medicinal cannabis.

4. Access to medicinal cannabis requires that patients have the opportunity to obtain medication appropriate for their individual medical needs. Medicinal Cannabis Dispensaries facilitate this by providing patients with have the option to access a variety of cannabis strains from a variety of licensed providers in order to determine which cannabis strains are optimally therapeutic for their medical needs.

5. Licensed dispensaries operating in overseas jurisdictions achieve this by:

   - providing information on different cannabis strains cannabinoid and terpene profiles;

   - provide horticultural information associated with the various strains supplied by commercial cannabis cultivators;

   - allow a patient to examine medicinal cannabis. The terpene profile in a plant responsible for its fragrant notes is relied upon by patient's as an indicator of the way in which the cannabis will react with their biochemistry, based on knowledge gained through prior exposure to such a strain. Different licensed producers will vary slightly in their horticultural practices and the strains they offer, which in turn will produce different fragrant notes and medicinal cannabis products. Having access to a variety of cannabis strains and the opportunity to inspect; and

- obtain information on the strain, ensures that diverse patient's medical needs are met.

6. Medicinal Cannabis Dispensaries favoured by this submission would also play an important intermediary role within the operation of medicinal cannabis schemes. Medicinal Cannabis Dispensaries would:

   - Monitor patient medicinal cannabis use on prescription;
   - liaise with the patient and their General Medical Practitioners / Medicinal Cannabis Practitioners regarding a patients health (if and where necessary);
   - assists licensed cultivators in strains selection for cultivation purposes to be supplied to the market, by providing information on the basis of customer demand projections generated from dispensary sales data;
   - provide storage facilities for a nominal fee to a patient for cannabis cultivated under a PPL or DPL(A), where desired;
   - play a regulatory role in monitoring supply of medicinal cannabis on prescription through checks, balances and discretionary powers being vested in dispensing practitioners to safeguard against unauthorized use and diversion to the illicit market.

7. Medicinal Cannabis Dispensaries would be registered with the Victorian Government and be required to hold relevant Commonwealth and State licenses that could be issued by the Victorian Government in the form of a Medicinal Cannabis Dispensary license (Dispensary License or "DL") which would authorise the lawful possession, processing, manufacture, administration, supply and sale of cannabis to patients, parents, guardians or carer holding an "Authority to Possess License'' with the designated code "APL" on a valid Medicinal Cannabis Card issued under the scheme.

8. In line with overseas jurisdictions and subject to alignment with Regulatory Objectives identified in this submission, the following measures could be considered for adoption into a medicinal cannabis model.

9. Personnel that might be considered for a dispensary license might include one or more of the following professionals:

   - Pharmacist;
   - General Medical Practitioner;
   - Chiropractor;
   - Dentist;
   - Registered nurse
   - Herbalist; and or
   - Naturopath.

10. These practitioners would be registered and issued with appropriate licenses with/by the relevant Victorian Government agency or department using their AHPRA registration and or registration number assigned to them for the purposes of the scheme.

11. The practitioners referred to could operate in the capacity as:

- a stand alone dispensary: or
- a as a Medicinal Cannabis Practitioner as a part of a Medicinal Cannabis Clinic or Compassion Club;
- part or an extension of a commercial production operation.

12. A stand alone dispensary or one that operates as an extension of a commercial production operation would offer services including but not limited to the following:

a. providing information on cannabis strains, cannabinoid and terpene profiles and cannabis products;
b. providing an opportunity to examine cannabis and cannabis products;
c. providing information associated with the production and supply of cannabis/cannabis products;
d. providing information on safe and effective use and/or administration of cannabis and cannabis products;
e. scrutinising and monitoring prescription and cannabis use under prescriptions;
f. supplying and selling authorised cannabis, cannabis products and paraphernalia under valid prescriptions to medicinal cannabis patients, parents, guardians or carers holding valid Medicinal Cannabis Card with appropriate licensing codes;

13. Authorised cannabis and cannabis products should be sold to patients, parents, guardians or carers at compassionate pricing. This should be made a regulatory requirement for the purposes of the scheme. A failure to do this and or inconsistencies in approaching compassionate pricing has been a criticism of current overseas models;

14. This submission considers that:

a. a stand alone dispensary and / or one operating as an extension of a commercial production operation would not have prescribing rights, with such rights being vested exclusively in a General Medical Practitioner or a Medicinal Cannabis Practitioner;

b. a patient, parent, guardian and or their care provider could register with one or more Medicinal Cannabis Dispensaries holding a valid DL, in order to acquire access to appropriate cannabis strains and or products needed for a patient's medical treatment; and

c. the registration process may be done online and or at the follow up consultation with dispensary staff. The registration process would include:

(i) the patient's, parent's, guardian's or carer's contact details;
(ii) the General Medical Practitioner or Medicinal Cannabis Practitioner contact details;
(iii) a patient's, parent's guardian's or carer's Medicinal Cannabis Card

details and personal identification code;

(iv) relevant medical information i.e. allergies, sensitivities, current medications, and contra indicated medications;

(v) obtaining relevant consents to liaise with the patients General Medical Practitioner and or Medicinal Cannabis Practitioners;

(vi) acknowledgement that the patient will use cannabis strictly in accordance with the dose and for the purposes prescribed and in doing so, taking full responsibility for the use and consequences of that use;

(vii) An agreement between the patient and Medicinal Cannabis Dispensary setting out the patient's rights and obligations.

d. a dispensary would have access to the Victorian Government electronic data base and could using the practitioners AHPRA and/or registration code issued for the purposes of the scheme, access the data base to verify whether the patient, parent, guardian or carer held a valid APL and or DPL (A) in the form of a valid Medicinal Cannabis Card, prior to supplying medicinal cannabis and /or cannabis goods under prescription to the patient;

e. a dispensary on confirming that a patient, parent, guardian or carer holds a valid APL and/or DPL (A) and Medicinal Cannabis Card could issue the patient with a dispensary code to identify the patient and patient purchases of cannabis and cannabis products under prescription, to the dispensary. This would be especially useful for inventory reconciliation purposes;

f. a dispensary code together with a password, personal patient information and or a combination of the same, could subsequently be used to supply and process prescriptions whether in store, online, or over the phone;

g. a dispensary could use the dispensary code and issue a patient with a dispensary card which the patient, parent, guardian or carer might use for:

(i) quick electronic identification; and / or

(ii) to enable secure entry and or exit from the dispensary; and/or

(iii) for scanning patient's cannabis purchases under prescription into the dispensary electronic sales system that could transfer that information into the electronic database housed by the Victorian Government which could be cross referenced to prescriptions issued for and on behalf of the patient.

h. an initial appointment with the dispensary for the purpose of a consultation would be desirable. At this consultation and subsequent consultations the dispensary could:

(i) access the electronic data base to verify the patient, parent, guardian or carer holds a valid APL and / or DPL (A) in the form of codes on a current Medicinal Cannabis Card;

(ii) access and check the date of the certification lodged by the patients general medical or Medicinal Cannabis Practitioner to determine whether a patient has been prescribed medicinal cannabis within 12 months of that certification. Where the patient has not and the certification is more than 12 months old, the dispensary would refer the patient back to the certifying General Medical Practitioner or Medicinal Cannabis Practitioner for recertification;

(iii) access prescriptions and or other licenses issued to the patient, parent, guardian or carer [i.e. PPL or DPL (A)] to determine the patients Maximum Total Daily Dose and what percentage of that dosage is authorised to be filled on prescription under the terms of a patients license(s);

(iv) ensure that a separate prescription has been provided for each form of cannabis medicine;

(v) ensure that the prescription specifies separate cannabinoids and expresses them as a ratio to one another;

(vi) confirm whether the existing prescription is valid (i.e. 12 months old) and that the patient copy corresponds with the copy housed on the electronic data base;

(vii) confirm whether the quantity of specific medicinal cannabinoids and their ratio to one another, together with any required terpenes on the patients prescription conform with the details in the prescription housed on the electronic data base;

(viii) consider and confirm that the forms of cannabis and or cannabis products on the patients prescription conform with the details in the prescription housed on the electronic data base;

(ix) ascertain at the point of dispensing, whether and how much of a patients Maximum Total Daily Dose over the prescription period, has been dispensed with reference to details housed in the Victorian Governments electronic data base, regarding prior dispensing activity for the patient. A patient can have their prescription filled in full or part, at more than one dispensary;

(x) note any change in a patient's symptoms or conditions and where necessary, refer the patient back to a patient's treating General

Medical Practitioner or Medicinal Cannabis Practitioner and and/or; dispense less than the prescribed amount if the health and best interests of the patient require such;

(xi) a dispensary practitioner would have the discretion to supply less than the amount prescribed for a patient where:

(i) there are discrepancies in one or more prescriptions that would take time to investigate and resolve prior to filling of the prescription;

(ii) the health interests of the patient require such; and or

(iii) the circumstances raise suspicion of unauthorized use or illegality;

(xii) provide the patient, parent, guardian or carer, with general information on cannabis, strains, cannabinoids, terpenes, safe cannabis use, methods of administration, instructions on dosage and correct application of dose and how to manage, track and record their symptoms with the selected strains. Patients without prior exposure to cannabis use would be noted, as well as those who may have had substance abuse issues, mental health problems and or any contra indicated conditions. These patients would be carefully monitored;

(xiii) where a General Medical Practitioner or Medicinal Cannabis Practitioner has failed to do so, special needs patient's could be identified (i.e. first time users, frail, those in palliative care, the elderly, persons with cognitive impairments) and this could be raised with the patients treating General Medical Practitioner or Medicinal Cannabis Practitioner for the implementation of a buddy monitoring program to ensure that someone can assist them in taking their cannabis medications. A dispensary could liaise with the patients treating General Medical Practitioner or Medicinal Cannabis Practitioner to arrange this. A dispensary could also assist a patient with these and other specific health challenges by referring the patients back to their treating practitioners, to appropriate health and community services and/or where the dispensary operates as part of a Medicinal Cannabis Clinic, it could directly refer patients to ancillary therapies and health services;

(xiv) carefully dispense cannabis and or cannabis products in a hygienic manner and in accordance with any occupational, health and safety regulations;

(xv) weigh and carefully measure all cannabis and cannabis products on

highly accurate pharmacy, industrial or similar grade scales, that are regularly calibrated and serviced;

(xvi) providing a patient with cannabis and or cannabis goods in sealed tamper proof and clearly labelled packaging that accords with regulations for the purposes of the scheme.

This submission consider that:

15. Medicinal Cannabis Dispensaries could provide patients with patient information sheets, (similar to those issued with current prescription products) containing information on the cannabis strain, together with instructions on safe use, dosage, possible adverse side effects and contraindications. [See: Annexure 1]. A patient could also be issued with a work sheet or book to record and monitor symptoms and the circumstances of any adverse reactions. A dispensary could make these tools readily accessible online on their websites and via ''online apps'';

16. a patient who due to physical infirmity and or geographical limitations, might consult a dispensary and dispensary practitioner using online electronic conferencing facilities such as "Skype";

17. a patient, parent, guardian and or their care provider holding a current Medicinal Cannabis Card and APL may register with one or more dispensaries in order to access cannabis strains and products suited to the patient's medical needs. Records of the total quantity of cannabis dispensed (up to the patients Maximum Total Daily Dose of medicinal cannabis over a 30 day prescription period) during the prescription period and would be housed on the Victorian Governments electronic data base;

18. on follow up consultations to fill prescriptions reference to a patient's record of their symptoms using cannabis strain(s) supplied under prior prescriptions would be reviewed together with the patient's current symptoms and reports concerning their prior cannabis use. Recommendations for and referral back to a patient's General Medical Practitioner or Medicinal Cannabis Practitioner could be arranged by the dispensary, if and when necessary, for adjustments to be made to prescriptions;

19 medicinal cannabis would be dispensed strictly in accordance with any regulations under the scheme and up to a patients Maximum Total Daily Dose over the prescription period, as authorised under the terms of one or more licenses held by the patient;

20. dispensaries and registered Medicinal Cannabis Dispensary Practitioners should have a general discretion to limit the quantities of medicinal cannabis dispensed under any prescription. Such a discretion would be appropriate where the patient's health was at risk and/or where there are legitimate concerns of unauthorised use or illegality. The discretion could be exercised by the practitioner until the dispensary had the opportunity to investigate the matters further;

21. as amounts of cannabis used by patient's can vary daily, weekly or monthly depending upon their health, dispensary staff should be made aware of such and any irregular or larger purchases of cannabis by a patient, parent, guardian or carer, that fall outside the parties general purchasing pattern, should be considered as a possible reflection of a patient's health needs, financial considerations and thereafter, as possible resale to unauthorised third parties. Dispensary practitioners would be encouraged to consult

such parties and/or seek confirmation from the patient's treating General Medical Practitioner or Medicinal Cannabis Practitioner;

22. after an initial consultation with a dispensary a patient could have their prescription filled by the dispensary online or by phone using the issued dispensary code, patient identifying information, any password or combination thereof, required for security purposes;

23. the dispensary could deliver medicinal cannabis discreetly by mail or courier service. Courier services associated with the dispensary should be discreet and free from advertising and or any identifying business logo or insignia that might identify the nature of the service provided and its association with a Medicinal Cannabis Dispensary;

24. all quantities of medicinal cannabis dispensed would be in accordance with a valid and current prescription and be recorded in both the dispensary records and in the electronic data base operated by the Victorian Government. Purchasing information at the point of sale on a sales invoices, could also be electronically entered into the dispensary records and transferred to the Victorian Government database. Such information could include: date and cost of purchase, the patient, parent, guardian or carer dispensary identification code and or personal identification code taken from their Medicinal Cannabis Card, together with the quantity, strain and batch identification number. This information would:

    - assist in identifying possible diversion to illicit markets;
    - assist in product recalls by dispensaries;
    - assist the dispensary to develop/make better therapeutic treatment recommendations;
    - assist the dispensary in their daily inventory reconciliations;
    - assist in the auditing process of dispensaries;
    - assist in the business development and management of the dispensary;
    - assist in providing information on efficacy which could further assist in scientific research;
    - assist commercial cultivators in selecting strains to provide to dispensaries, based on demand/need.

25. all quantities of medicinal cannabis to be dispensed would be carefully weighed on pharmacy, industrial or similar grade scales that are regularly calibrated and serviced, with attention to hygiene and safe storage of cannabis and recorded for the purposes of daily inventory reconciliation, as well as subsequent auditing purposes. Allowance, (via a specific mathematical calculation), should also be made to accommodate moisture loss from cannabis and cannabis products that will alter weight/quantity in inventory records and otherwise affect reconciliation outcomes. This measure would ensure that accurate inventory reconciliations can be obtained;

26. details of nitrogen filled tamper sealed bags or similar [531] used to deliver cannabis to the dispensary, together with all cannabis goods received would be recorded in an appropriate register identifying: supplier details, quantity and date received, batch number, date of deliver, strain type and cannabinoids composition and ratio of THC to other cannabinoids. This would be used for audit and risk management purposes i.e. for a possible product recall;

27. patients, parents, guardians or carers that do not appear in the Victorian Government

database but hold Medicinal Cannabis Cards issued in other jurisdictions could use Victorian dispensaries. Victorian dispensary would however require prior approval from the Victorian Government, before dispensing medicinal cannabis to verify the patient's standing as a medicinal cannabis user in another jurisdiction, domestic or international;

28. cannabis and any other cannabis products entered into the relevant inventory register and stored in sterile containers and or in fridges at the relevant temperatures to ensure freshness and avoid spoilage. Products that show signs of deterioration and/or have been exposed to a non sterile surface or environment, could be set aside, destroyed and accounted for in a manner provided by appropriate regulations;

29. all cannabis and cannabis products should be kept, at all times, in secure locked locations on the premises, with access to such products restricted to nominated staff;

30. dispensaries might also hold retail licenses to sell cannabis products, cannabis paraphernalia and/or other therapeutics, approved for over the counter sale in Victoria;

31. that license application and selection criteria could include and or be subject to the following:

    a. stipulating whether the dispensary is a stand alone operation or part of a licensed commercial producer or manufacturing operation for cannabis and or cannabis products, a Medicinal Cannabis Clinic or a Compassion Club;

    b. suitability and location of the premises: no store front operations; attendance to security for staff and customers i.e. secure access to the building, video surveillance, alarm/monitored alarm systems, appropriate fencing, lighting, loitering avoidance measures, secure transportation facilities;

    c. applicants and staff would be screened to determine whether they were ''fit and proper persons" to supply or sell medicinal cannabis and cannabis products;

    d. the applicants capacity to provide medicinal cannabis and cannabis products at compassionate prices;

    e. the financial stability of the applicant;

    f. the suitability and financial stability of the business model submitted with the license application;

    g. the skill and experience of the applicant including their ability to operate a viable Medicinal Cannabis Dispensary;

    h. the skill, experience and or knowledge of the applicant, associated with cannabis and/or whether they had obtained any accredited training qualifications in relation to medicinal cannabis that might required by the Victorian Government;

    i. the skill, experience and or knowledge of the applicant involved in the dispensing of medication or therapeutic substances;

j. the submission of general quality assurance standards, processing, occupational health and safety, auditing, security and risk management plans accompanying any license application;

k. if operating a dispensary alongside a licensed cultivation operation at the same or a separate premises: proximity to patients and/or access to medicinal cannabis and cannabis products and/or alternatively,(after completion of the registration process referred to previously), a means whereby such could be made available to patients via mail or courier services which could be arranged online or via phone;

l. ability to provide an online electronic platform for patients, General Medical Practitioners and Medicinal Cannabis Practitioners, with regularly updated information on: strains of cannabis available and the associated laboratory data demonstrating quality, cannabinoids and terpene content and potency, together with the presence of any contaminants / chemicals / mould / fungi / bacteria detected.

m. ability to provide a secure and discreet electronic online platform to enable the purchase of medicinal cannabis products by patients, parents, guardians or carers registered with the dispensary and holding a valid APL and Medicinal Cannabis Card, with provision for secure and discreet shipping to such or to their General Medical Practitioner or Medicinal Cannabis Practitioner.

32. In addition to adhering to the above matters, License and license renewal might operate subject to the following regulatory conditions, obligations and restrictions:

:

a. holding and retaining licences for manufacturing cannabis products and /or an appropriate retail license for sale and supply of approved cannabis products;

b. the supply and sale of medicinal cannabis and medicinal cannabis products being made exclusively to patients, parents, guardians and or their care providers under a current Medicinal Cannabis Card and APL using their identification number on the card and confirming such by accessing the Victorian Government electronic data base with the practitioners AHPRA or other registration number issued to them for the purposes of the scheme;

c. the supply and sale of medicinal cannabis and medicinal cannabis products on a valid prescription up to the percentage of the patients MTDD operating under the terms of the patients license;

d. individual patient consultations being strictly by appointment only so that patient's can be provided with any and all necessary information on cannabis use, methods of administration, selection of appropriate strains and managing and tracking their symptoms with the selected medicinal cannabis strains, reviewing any changes to symptoms and or otherwise assisting the patient with any specific challenges associated with medicinal cannabis use;

e. compliance with the submitted general quality assurance standards, processing, occupational health and safety, auditing, security and risk management plans submitted with the license application;

f. adherence with appropriate security measures such as: video surveillance, alarm/monitored alarm systems, appropriate fencing, lighting, loitering avoidance measures;

g. adherence to security, tracking and or inventory/auditing measures of cannabis produced to avoid theft and diversion to the illicit market. In the case of a commercial producer and dispensary, this could include measures currently employed in overseas jurisdictions including: RFID chipping of flowers and plant from seed to sale, to account for all quantities of cannabis cultivated, processed, stored, distributed and sold;[532]

h. all quantities dispensed in accordance with a valid and current prescription are to be recorded, including at the point of sale on a sales invoice, with the data being electronically transferred to the Victorian Government electronic database as discussed above;

i. daily reconciliation of inventory and sales;

j. batch identification corresponding to numbered sealed tamper proof bags containing medicinal cannabis and / or cannabis products, both numbers being traced through tracking and inventory system from cultivation to laboratory and to point of sale;

k. batch identification and numbered medicinal cannabis supply bags or cannabis products to correspond with and be clearly identified on any dispensing containers, vessels, shelf and storage locations, in which the same is housed at the dispensary for tracking, inventory and audit purposes;

l. regular inventory reconciliation statements to be lodged electronically with the relevant Victorian Government agency or department established for administering the scheme;

m. annual auditing, together with the occasional ''on the spot audit'' of inventory, financial records and premises. Record keeping and the auditing process would also include compliance with S 23 Narcotic Drugs Act 1967 (Cth) and submission of such records /reports and returns to be provided to the Commonwealth Secretary with respect to manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;

n. mandatory reporting of discrepancies, unusual waste, total destruction of inventory, disappearance of inventory and suspected thefts, to the relevant Victorian Government agency within 24 hours or the relevant Victorian Government agency or department(s) established for administering the scheme within 72 hours;[533]

o. providing notice to the relevant Victorian Government agency or departments of a change in the license holders name, address, operational and storage site, together with proof of the same;

p. adherence to regulatory compliance matters, relevant quality assurance standards, inventory checks and record keeping required by Victorian and or Commonwealth Laws or by the Victorian Government agency or department established for administering the scheme and/or Local Municipal Councils;

q. maintaining an online electronic platform for patients, General Medical Practitioners and Medicinal Cannabis Practitioners, with regularly updated information on: strains of cannabis available; the cultivators/suppliers details and the associated laboratory data demonstrating quality, cannabinoids and terpene content and potency, together with the presence of any contaminants / chemicals / mould / fungi / bacteria detected;

r. Where patients store cannabis grown under a PPL or DPL(A) up to their permitted storage quota with the dispensary, such cannabis is to be clearly discernable and kept separate and securely stored away from cannabis acquired from commercial sources for retail supply. A register associated to the storage of the cannabis would be kept and the reconciliation inventory processes referred to above would apply and be recorded in the individual register. The register would be available for inspection of the PPL or DPL(A) license holder upon request;

s. maintaining separate registers of all cannabis and cannabis product types received and supplied from commercial producers, al third party cultivators manufacturers or other dispensaries, with details including but not limited to:

    - date of packaging of cannabis and cannabis products;
    - batch and or registered supply number on the cannabis sealed and tamper proof/tamper evident bags and packaging, together with any other product identification numbers and or details;
    - best before/expiry date of cannabis and cannabis products;
    - date of receipt of delivery of cannabis and cannabis products with reference to suppliers invoice details;
    - the type of cannabis and cannabis products received (i.e. strain type and references to their laboratory certified cannabinoid and terpene profile, with percentages of THC and its ratio to other cannabinoids, referenced to the product) with sufficient details to identify the same from specific batches of cannabis and or packaged cannabis products;
    - the exact quantity of cannabis and cannabis product (as stated in details provided by the supplier or manufacturer), together with the

exact weight as determined by the dispensary having weighed the cannabis and cannabis products on pharmacy or industrial grade calibrated and regularly serviced scales, after taking delivery thereof. Subsequent results would account for moisture loss and would be recorded for inventory reconciliation and risk management purposes;

- producer/distributor (i.e. holding a CPL, PPL or DPL or another dispensary) or manufacturer's details;

- the corresponding information referred to in the materials above, to be cross referenced to and clearly marked on, all inventory vessels housing cannabis and cannabis products dispensed from suppliers and manufacturers;

- the cultivation site location and/or site cannabis or cannabis products were distributed from;

- all laboratory reports issued with regard to the cannabis and cannabis products received from by the producer/manufacture;

- the health of the cultivators crops, chemicals/pesticides used and at what stage (if and where known), cross referenced to any relevant laboratory reports relevant to the crop/batches associated to the cannabis and cannabis products received;
- cost of together with invoice receipt numbers;

- any other information for the purposes of inventory reconciliation, tracking, audit and possible product recall;

- substandard and/or damaged cannabis and or cannabis products with details thereof together with date and arrangements made for secure return of the same to the supplier and/or manufacturer and the details of receipts associated with such returns. Such information would be cross referenced to inventory records for audit purposes.

t. maintaining separate registers containing details of each commercial producers, designated license producers, manufacturers and other dispensaries, who supply cannabis and or cannabis products to the dispensary. Particulars for entry into the register might include:

- details of suppliers and manufacturers;

- the cannabis and cannabis products that the supplier and/or manufacturer has delivered to the dispensary and under what type of license (i.e. CPL, DPL or PPL) together with the registration numbers associated with such licenses;

- cultivation, curing and storage techniques (if and where known and to the extent permitted that does not infringe upon proprietary trade secrets of the suppliers business);

- adherence to quality assurance standards and protocols and the conditions of the growing site and or premises as evidenced by a certificate of satisfaction issued from an annual audit of the producers operations or from inspections carried out by the relevant Victorian Government agency, department or Local Municipal Council;

- any reports of or evidence of mould, mildew, fungi or bacteria, chemicals, heavy metals and/or other contaminants and;

- reports of any breaches of standards or contractual terms/and or termination of contracts; with such information being made available via the relevant Victorian Government Agency, department or Local Municipal Council responsible for site inspections and the administration of the scheme.

The contents of this register would be regularly maintained and would be required to be made available for auditing purposes or for the inspection of any patient, parent, guardian or carer registered or having been registered with the dispensary;

u. maintain a separate register of all laboratory certifications relevant to:

   i. each cannabis crop batch testing; and

   ii. retaining copies of such laboratories annual certificates of compliance with quality control standards (such as calibration of laboratory equipment used to identify plant components and cannabinoid potency) and making such available for the inspection of patients, parents, guardians or carers who are or have been registered with the dispensary and/or their General Medical Practitioner or Medicinal Cannabis Practitioners;

v. batch testing by the dispensary of any cannabis representing excess cannabis yield over permitted storage quotas, purchased by the dispensary before being supplied and sold through the dispensaries operations under prescription. Batch testing along the following lines would be desirable: testing from a number of different areas of a number of flowers from a plant(s) of a specific crop batch, undertaken through specific accredited medicinal cannabis laboratories for:

   a. flower appearance (rating);
   b. cannabinoid & terpene profile;
   c. cannabinoid content and percentage relevant to other cannabinoids present;
   d. absence of hairs, insects, bacteria, fungi, pesticides, chemicals, heavy metals, mould;
   e. any other contaminant;

w. laboratory reports on all cannabis strains available for purchase through the dispensary, with the disclosure of: chemicals used in the growing process and/or otherwise detected in the plant, together with the detection of any bacteria, fungi, mould, heavy metals or other plant diseases would be:

i. kept in the relevant cannabis product register; and

ii. published on an electronic platform for the benefit of patients, parents, guardians, carers, General Medical Practitioners, Medicinal Cannabis Practitioners, and the scientific community, where it is to remain for a designated period of time;

x. laboratory reports and/or general information on cannabinoids and their ratio to one another, together with terpenes specific to a particular strain and batch in stock at the dispensary, and general information on such, to be:

i. kept in the relevant cannabis product register; and

ii. published on an electronic platform for the benefit of patients, parents, guardians, carers, General Medical Practitioners, Medicinal Cannabis Practitioners, and the scientific community, where it is to remain for a designated period of time;

u no direct or indirect advertising and marketing to patients, parents, guardians or carers and or promotion of cannabis or cannabis products associated to medical conditions. [534]Publication of scientific literature on various cannabis strains and forms is permitted, but statements and or information otherwise making specific health claims would not be;

v. maintaining an electronic online platform:

a. providing patients, parents, guardians or carers with secure and discreet access to register and have prescriptions dispensed online; and

b. with current information pertaining to strains of cannabis and cannabis products being sold and supplied, together with relevant laboratory reports and any other information required by regulations under the scheme;

w. holding and maintaining current professional indemnity, public, business risk and product liability insurance policies;

x. providing patient's with patient information sheets on general safe use, warnings, contra indications, possible side effects and similar information. **[See: Annexure 1]**

33. Revocation of a Medicinal Cannabis Dispensary License might occur where:

- the license holder requests the revocation;
- the license holder was not eligible to hold a DL license;
- the license was obtained on false or misleading information;
- the license holder failed to obtain or retain other relevant licenses (if any) under the scheme;
- the holder looses the right to hold their professional license;

- the license holder has breached one or more of the conditions referred to at paragraph 32 without reasonable cause;

34. Revocation of a Medicinal Cannabis Dispensary License would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and

- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process;

35. Where a license is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return the relevant license within 30 days of receiving the notice referred to at paragraph 34 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively;

36. Where a license holder wishes to challenge the reasons for the license revocation, forfeiture of the license would take place at the conclusion of any review or appeal process, where the outcome did not favour the license holder.

MEDICINAL CANNABIS CLINICS

1. Under the current model favoured by this submission, a Medicinal Cannabis Clinic would employ practitioners who would be able to determine and certify whether a patient meets the lawful access criteria for entry into a medicinal cannabis scheme and proceed to treat and prescribe medicinal cannabis for the patient.

2. In line with overseas jurisdictions and subject to alignment with stated Regulatory Objectives, the following are elements offered for consideration as a part of a Medicinal Cannabis Clinic under a proposed scheme.

3. A Medicinal Cannabis Clinic ("clinic") would be registered and issued with appropriate Commonwealth and Victorian licenses by the relevant Victorian Government agency or department responsible for the administration of the scheme.

4. License issue and renewal for a clinic would be dependant upon the issues discussed below. A clinic, for the purposes of the scheme could operate with or without a licensed dispensary and may take the form of:

   i. a Medicinal Cannabis Clinic as a stand alone business operation; or

   ii. a Medicinal Cannabis Clinic as a part of a general medical practice; or

   iii. a Medicinal Cannabis Clinic as a part of a Compassion Club or Co-operative.

5. Insofar as a clinic might also operate as a dispensary, the same considerations discussed in this submission regarding dispensary operations would also apply to the dispensary operating in association with the clinic. Similarly, considerations discussed in this submission with to regard Compassion Club or Co-operatives, would also apply to clinics operating within such a framework.

6 A clinic would be staffed by one or more of the following Medicinal Cannabis Practitioners:

- General Medical Practitioner;
- Herbalist;
- Naturopath;
- Pharmacist;
- Chiropractor;
- Registered Nurse;
- Dentist.

7. Medicinal Cannabis Practitioners would hold valid Licences from the Victoria and Commonwealth Government to posses, use, manufacture and administer medicinal cannabis, as and where appropriate. An amendment to the Drugs Poisons and Controlled Substances Act 1981 (Vic) could vest prescribing rights in these practitioners for the purposes of a medicinal cannabis scheme. As to the appropriate placement of such professionals in this role, the Commission is referred to previous remarks in this submission at: "Authorizing and Prescribing Medicinal Cannabis".

   Over time, and with the introduction of an appropriate accredited course the list of persons who might operate as a Medicinal Cannabis Practitioner, could be added to include other allied health professionals and persons. Until such a course is operational it is considered that the professionals identified would be more than competent to execute the responsibilities required under the scheme, in the interim period. The Commission is referred to previous remarks in this submission at ""Authorizing and Prescribing Medicinal Cannabis".

8. Medicinal cannabis practitioners could be registered with the relevant Victorian Government agency or department responsible for administering the scheme, under their AHPRA registration number and or any other registration number issued to them under the scheme.

9. A Medicinal Cannabis Practitioner could attend to the following matters:[535]

   9.1 record a patient's personal details and medical history in a registration process. Such information might include:

   - Name
   - Address
   - date of birth
   - emergency contact details
   - medical conditions and symptoms
   - medications
   - pregnancy status
   - allergies/sensitivities
   - appetite

- sleeping habits
- prior cannabis use
- patient's personal identification code from the Medicinal Cannabis Card and copy of the card
- date of certification under the scheme

9.2 record details of the patient's General Medical Practitioner (responsible for certification) details:

- name
- address
- telephone and email details
- AHPRA registration details

9.3 request the patient to complete a registration and patient history form with appropriate consents to:

a. obtain and access information from the patient's General Medical Practitioner, specialists or other allied health care professionals (if and when required), as well as the Victorian Government to access the electronic database; and

b. source and supply medicinal cannabis and or cannabis products, for and on behalf of the patient, for exclusive medicinal use of the patient only with the patient undertaking to accept all responsibilities and any associated risks involved in such therapy;

- The registration document could also contain:

c. a statement of patient rights which would include patient confidentiality, rights consistent with those in the Australian Charter of Health Care Rights as well as;

d. the patient's responsibilities i.e. no use of medicinal cannabis at or outside the Medicinal Cannabis Clinic, the building it is located in or surrounds;

e. the rights of the clinic: circumstances in which the clinic might opt to exercise the discretion to terminate treatment;

f. an estimate of costs associated with treatment.

9.4 determine whether the patient, parent, guardian or carer holds a valid APL, in the form of a Medicinal Cannabis Card and or other license encoded thereon, by:

a. authorising the Medicinal Cannabis Practitioners AHPRA registration and or registration number for the purposes of the scheme, together with the patient's personal identification number on their Medicinal Cannabis Card, identify the patient, parent, guardian or carer in the Victorian Government electronic database; and

b. where a patient, parent, guardian or carer's details do not appear in the electronic database and such a party holds a Medicinal Cannabis Card and/or holds a Medicinal Cannabis Card issued from another domestic or international jurisdiction, the Medicinal Cannabis Practitioner would contact the relevant Victorian Government agency or department responsible for administering the scheme, before proceeding further and with respect to patients from other jurisdictions, seek special authorisation to treat such patients[536]. This would enable monitoring for potential diversion to the illicit market.

9.5 Where a certification is found on the electronic data base and details identifying the patient housed therein correspond with the Medicinal Cannabis Card held by the patient, the Medicinal Cannabis Practitioner could:

1. check the date of certification authorising entry into the scheme and;

2. If the patient's condition and symptoms are present and the certification is less than 12 months old, the practitioner could proceed to treat and prescribe medicinal cannabis for the benefit of the patient; [See: paragraph 15(b) at "Authorising and Prescribing Medicinal Cannabis'' in this submission.] [537]

3. Where the patients condition and symptoms are present and the patient has not been treated by a General Medical Practitioner or a Medicinal Cannabis Practitioner and the certification is greater than 12 months old, a new certification would be required prior to proceeding to treat and prescribe medicinal cannabis for the patient;

4. confirm general details in the electronic data base with any other information provided by the patient, parent, guardian or carer, to ensure they correspond with details lodged electronically; and

5. report discrepancies and liaise with the patient, parent, guardian or carer, their General Medical Practitioner, and relevant Victorian Government agency or department to correct the same;

9.6 where a patient requires certification for the purposes of registration and entry to the scheme and:

a. was unable to obtain such from a General Medical Practitioner; or

b. a pre existing certification had expired;

a Medicinal Cannabis Practitioner could, relying on the completion of a relevant statement or a letter from a patient's General Medical Practitioner lodged online and appearing on the electronic data base, or otherwise having been provided to the Medicinal Cannabis Practitioner stating:

a. the doctor had reviewed the patients medical history; and

b. the patients medical condition and or symptoms; and

c. that the doctor has performed a complete medical examination and was satisfied with the same; and

d. any relevant considerations arising out of that medical examination;

proceed with the certification process.

9.7 The Medicinal Cannabis Practitioner would then where the patient provided the letter referred to:

(i) confirm in writing with the patients General Medical Practitioner the health information provided in the letter and thereafter;

(ii) attend to the certification process by determining whether:

- the patient had a medical condition or symptoms involving pain and or suffering which could be assisted by prescribing medicinal cannabis; and

- accessing the electronic data base, complete the certification process certifying that the patient is eligible to lawfully access cannabis under the scheme.

Medicinal cannabis practitioners could be assisted in this determination by being provided with materials similar to those offered to medical practitioners in Canada by Health Canada, under the operation of its medicinal cannabis program. It would be desirable for such practitioners to also undergo appropriate medicinal cannabis education and or accreditation, when such is made available. It is suggested that all practitioners (including General Medical Practitioners) should be required to participate in such as a condition of their professional license renewal.

9.8 the certification process would be completed by the Medicinal Cannabis Practitioner on the electronic data base operated by the Victorian Government, using the practitioners AHPRA registration number and any other issued to the practitioner for the purposes of the scheme;

9.9 a copy of the certification could be printed for the patient's records and an additional copy provided to the patient for the purposes of assisting them make application for entry into the scheme;

9.10 the patient, parent, guardian or carer could then make application to the relevant Victorian Government Agency or department administering the scheme, for the issue of an APL in the form of a Medicinal Cannabis Card and or any other license(s) required, that would be encoded thereon.

9.11. A Medicinal Cannabis Practitioner once satisfied that:

a. a current certification is in operation; and

b. a patient, parent, guardian or carer holds a valid APL or Medicinal Cannabis Card and/or other licenses could proceed to usher the patient, parent, guardian or carer through an ‘’intake process’’ and attend to designing a medicinal cannabis treatment plant for the patient, before proceeding to prescribing medicinal cannabis.

10. At the intake process the clinic could:

10.1 issue a patient, parent, guardian and/ or carer with the Medicinal Cannabis Clinic/dispensary card for quick electronic identification of the card holder and also for the secure entry to, and exist from, the clinic in a manner similar to an electronic swipe card. It could also be used where the clinic operates a dispensary to scan a patient’s cannabis purchases into an electronic database at point of supply and sale.

10.2 use the intake/registration procedure to educate all new and or existing patients, parents, guardians and/or carer’s operating under the scheme on:

a. medicinal cannabis and cannabis products, the variety of strains and therapeutic effects relevant to addressing a patients medical condition;

b. the safe and effective use of medicinal cannabis, its forms and application methods;

c. various medicinal cannabis devices used to administer medicated doses and how to effectively use the same;

d. potency, potential risk for substance abuse (where appropriate);

e. possible adverse or undesired effects from use and how to manage the same;

f. contra indications (if any);

g. possible drug interactions (if any);

h. safe and responsible use (i.e. not when driving, using heavy machinery etc.);

i. social, legal and political issues (i.e.: where use is not permitted, regulatory requirements regarding possession and use, as well as law enforcement procedures/protocols).

11.1 After the completion of an intake process, the Medicinal Cannabis Practitioner could attend to tailoring a medicinal cannabis treatment plan for the patient. This might also involve the following:

a. checking the date of certification. If condition and symptoms are present and certification is less than 12 months they would proceed to treat and prescribe;[538]

b. confirming the medical history and general details with the patient and liaise with a patient's General Medical Practitioner, if and where necessary in the event of discrepancies;

c. considering possible contraindications and identify at risk patient's i.e. history of substance abuse or dependency, family history of mental illness, nausea in pregnancy – considering risks and benefits;

d. identifying and giving priority to time critical patient's i.e. terminal and palliative care, in order to provide expedient treatment and care;

e. identifying and establishing patient's prior use of cannabis, tolerance and possible risk factors;

f. advising of any potential side effect and or risks that patient may suffer;

g. developing a personalized treatment plan based on patient's individual medical and personal comfort needs. Consideration might be given to: various strains of cannabis, forms, methods of application cultural heritage and dosage regimes (including Maximum Total Daily Dose or MTDD and Total Daily Dose or TDD where titrating towards a MTDD) and impact on lifestyle;

h. identifying the likely duration of the patients treatment and scheduling reviews;

i. employing a monitoring protocol to treat vulnerable patients. This could involve arranging for a care provider or suitable third party to oversee and assist with the patient's use and effects of initial dosing in particular, palliative care patient's, elderly and mental health patients. The patient, would be followed up at regular scheduled intervals to assess management and patient comfort, in order to address concerns and make any necessary alterations;

j. explaining potential side effect to the patient and in the case of a child the child's parents/guardians or carer on recipient of Medical Power of Attorney;

k. obtaining the consent in writing, from guardians and carers, for such parties to serve as primary administrator of medicinal cannabis therapy and control acquisition, possession, dosage and frequency of use, as directed and prescribed by the Medicinal Cannabis Practitioner;[539]

l. identifying suitable cannabis strains and products to address health concerns, together with appropriate therapeutic forms having reference to the patient's particular health issues and lifestyle considerations;

m. discussing and ensuring that the patient, parent, guardian and/or carer is familiar with and or understands: safe use, dosage, dosage titration, administration, possible adverse or undesired side effects and how to address the same;

n. Issuing the patient with an information sheet providing general information on safe use, warnings, contra indications, and possible side effects. **[See: Annexure 1];**

o. ensuring a patient knows how to dose and is comfortable with using apparatus to deliver cannabis medicine (if applicable);

p. encouraging the patient to keep and record a symptom diary, identifying symptom response after dosing. The clinic could provide work books, sheets and or electronic ''apps'' to assist patients with this exercise. Such could also be used, with the patients, parent, guardian or carer's consent, for scientific research purposes;

q. issue and prescribe medicinal cannabis. Prescriptions would be valid for 12 months and could be used by a patient, parent, guardian or care provider in association with, an APL represented by the issue of a current Medicinal Cannabis Card identifying the patient. No repeat on initial prescription(s) would be issued unless and until, the Medicinal Cannabis Practitioner was satisfied with the patient's ability to manage and tolerate dosage and any unwanted side effects;

. Each prescription[540] issued would set out:

(i) the patient's Maximum Total Daily Dose (''MTDD'') in grams of cannabis flowers and or mcg's of cannabinoids;

(ii) each specific measure of each and every cannabinoid as a ratio to other cannabinoid;

(iii) terpene requirements or restrictions (i.e. No Myrcene to avoid drowsiness or high Pinene to aid cognition / avoid memory loss);

(iv) product and form (i.e. flowers, concentrates, extracts, tinctures, edibles);

(v) methods of administration;

(vi) direction as to when to take the specific cannabinoids i.e. 3mg of Indica flowers 1 hour before bed; 3mg of Sativa flowers 3 x per day or 8 hr. intervals;

(vii) directions for use and dosage schedule for each cannabinoid which is required to be taken separately i.e. the period of time between doses for the different cannabinoids;

(viii) where more than one form of cannabis is recommended: whether prior cannabis medicines are to be maintained, reduced or discontinued;

(ix) where more than one form of cannabis is to be taken: separate prescription for each form of cannabis to be used by the patient;

. Total medicine to be dispensed under a prescription would equate to a patient's specified Maximum Total Daily Dose over the duration of the prescription period, (i.e. 30 days) having reference to all cannabinoids and all forms used, all prescriptions issued and in accordance with licenses held;[See: "Processing and Distributing: Medicinal Cannabis Dispensaries."]

The following information would also be required to complete the prescription:

(x) practitioners license identification code;
(xi) patient details: name, address, date of birth;
(xii) patient's personal identification code from their Medicinal Cannabis Card;
(xiii) date of prescription and expiry;
(xiv) number of repeats (5 as for standard medications associated with chronic medical conditions).

Separate prescriptions for each cannabinoid medicine and administration method ensure:

- accurate dosage for patients;
- the avoidance of errors by a doctor or Medicinal Cannabis Practitioner in dosing and leaving a patient without sufficient medicine;
- makes dispensing and tracking of cannabis provided to a patient easier and reflects current pharmacy practices in the dispersing of medications.

11.2 The Medicinal Cannabis Practitioner could:

a. complete a prescription form accessible from the electronic database operated by the relevant Victorian Government. agency or department responsible for the administration of the scheme via a special portal in the database, accessible with the practitioners AHPRA registration number or other relevant registration number provided for the purposes of the scheme. A copy would be automatically saved on the electronic database where it could then be accessed by other medical practitioners, hospitals, dispensaries and law enforcement agencies; and

b. provide a hard copy of a prescription to the patient, parent, guardian and/or their carer for presentation at a Medicinal Cannabis Dispensary;

c. issue an updated prescription should a patient require an increase in their daily prescribed dose at a future time;[541]

d. recommend and/or refer the patient to other therapeutic providers and or services within or outside the centre that would assist the patient with their treatment objectives;

e. refer and/or arranging essential social services for patient's in need (i.e. palliative care, home nursing care, general help, social security etc.).

11.3 General medical practitioners or Medicinal Cannabis Practitioners would set out a medicinal cannabis treatment plan. This plan would contain:

- duration of the treatment plan – up to 12 months;
- commencement date of the treatment plan;
- scheduled review dates under the treatment plan;
- a patients Maximum Total Daily Dose ("MTDD");
- a patients Total Daily Dose, where dose is being slowly titrated up to MTDD;
- forms of cannabis;
- recommended cannabis strains;
- dosage instructions;
- patient information sheet; [See: Annexure 1);
- instructions on how to deal with unwanted side effects (if any);

11.4 A General Medical Practitioner or Medicinal Cannabis Practitioner would access the electronic data base and complete a relevant form stating the duration of the patients treatment plan, including the patients Maximum Total Daily Dose. This information would be used to assess and assist the relevant Victorian Government agency or department in the issue and regulation of Medicinal Cannabis Cards and licenses under the scheme.

11.5 Patients, who have received a treatment plan from a Medicinal Cannabis Practitioner, and who are frail, have mobility difficulties or live in geographically remote locations, may have future consultations via electronic online conferencing platforms.

12. The following considerations would be relevant for the issue of relevant licenses to Medicinal Cannabis Clinics, for the purpose of a medicinal cannabis scheme:

- appropriate professional qualifications of the practitioners to be employed by the clinic;
- professional qualifications and submission of a current AHPRA or professional association license or registration number;
- the skill, experience an /or knowledge of the practitioners to be employed in the clinic generally and also with regard to medicinal cannabis;
- suitability of location and premises, if associated with a dispensary; [See: "Processing and Distribution: Medicinal Cannabis Dispensaries" in this submission]
- submission of general quality assurance standards, occupational health and safety and risk management plans;
- financial stability of applicant and the applicants business model, (especially important if operating as a dispensary and or as a part of a Compassion Club or Co operative);
- skill and experience to operate a viable business and medicinal clinic;

- suitability of staff and whether they are considered 'fit and proper persons" to supply and/or administer medicinal cannabis (especially where the clinic operates as a part of a Medicinal Cannabis Dispensary);
- considerations relevant to Medicinal Cannabis Dispensaries previously discussed, if the business model also involves a dispensary as a part of a clinics operations;
- considerations relevant to a Compassion Club or Co-operative where the clinic is to form a part of such an operation; [See: "Process and Distribution: Compassion Clubs and Co-Operatives" in this submission.]

13. Licenses might operate subject to the following conditions, obligations and restrictions:

- retaining professional qualifications;
- retention of current professional indemnity insurance;
- retention of a current and other relevant insurance policies including, public and product liability insurance (where relevant to dispensary operations);
- continuing professional education in the practitioners professional discipline,
- mandatory continued cannabis education working towards an accreditation under a recognised cannabis educational program;
- holding and retaining relevant licenses issued by the relevant Victorian Government agency or department responsible for administering the scheme, where a clinic also operates a dispensary, manufacturing operation and or Compassion Club/Co-Operative;
- compliance with record keeping and auditing processes regulations made in accordance with S 23 Narcotic Drugs Act 1967 (Cth) by submitting records /reports and returns (as required) to the Commonwealth Secretary regarding manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;
- where a Medicinal Cannabis Clinic also operates a Medicinal Cannabis Dispensary: requirements and considerations relevant to licensing, licensing renewal and operating a Medicinal Cannabis Dispensary, as set out at "Processing and Distribution: Medicinal Cannabis Dispensary" in this submission; and
- where the Medicinal Cannabis Clinic establishes a Compassion Club/or Co-operative: requirements and considerations relevant to licensing, licensing renewal set out at "Processing and Distribution: Compassion Clubs and Co-Operatives" (below) in this submission; and

- where the Medicinal Cannabis Clinics Compassion Club and or dispensary wish to manufacture cannabis products: requirements and considerations relevant to licensing, licensing renewal and operating manufacturing activities set out at "Manufacturing Cannabis Products" (below) in this submission; and
- adherence to regulatory compliance matters;

14. Revocation of a Medicinal Cannabis Clinic License might occur where:

- the license holder requests the revocation;
- the license holder was not eligible to hold a license;
- the license was obtained on false or misleading information;
- the license holder failed to obtain or retain other relevant licenses (if any) under the scheme;
- the holder looses the right to hold their professional license;
- the license holder has breached one or more of the conditions referred to at paragraph 13 without reasonable cause;

15. Revocation of a Medicinal Cannabis Clinic license would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and

- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process;

16. Where a license is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return the relevant license within 30 days of receiving the notice referred to at paragraph 15 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively;

17. Where a license holder wishes to challenge the reasons for the license revocation, forfeiture of the license would take place at the conclusion of any review or appeal process, where the outcome did not favour the license holder.

COMPASSION CLUBS & CO-OPERATIVES

1. The ability to provide access to medicinal cannabis is the most important operational aspect of any medicinal cannabis scheme. Personal Production Licenses ("PPL"), an Authority to Designate Production under a License ("DPL (A)") and Designated Production Licenses ("DPL") recognize this and facilitate access.

2. Patients, parents, guardians and cares who rely on DPL (A)'s must be able to engage registered individuals and commercial producers holding DPL's to grow cannabis on their behalf. However, the capacity of commercial producers to grow cannabis for such parties under a DPL will be limited. A patient's ability to locate an individual holding a DPL to grow cannabis on their behalf could also be difficult and/or such a cultivator's capacity to assist the patient might also have reached their lawful limitations. Compassion Clubs or Co operatives ("Compassion Clubs') could assist patients who are faced with these circumstances.

3. Compassion Clubs would play a large role in providing access to medicinal cannabis for patients holding a DPL (A). In jurisdictions overseas, these clubs operate so as to enable patients to have access to a large number of divergent cannabis medicinal strains that are cultivated exclusively for that club by third party cultivators, in accordance with strict quality control standards. Compassion Clubs not only arrange for cultivation via third party producers, but they can offer a wider variety of cannabis strains than a commercial producer would be able to. This is an important fact that must be recognised by any scheme. Access under a medicinal cannabis scheme must be authentic, in that it must provide access to cannabinoid medicines in the correct strains and cannabinoid ratio's relevant to a patients medical condition. Anything that falls short of this requirement will fail to provide adequate access to cannabis for medicinal purposes to relieve pain and/or suffering.

4. At harvest, a Compassion Club accepts delivery of the yield and after it is thoroughly tested for contaminants and its cannabinoid content and terpene profile, it is distributed via a dispensary operation to its membership at below the costs of the retail prices offered for medicinal cannabis by commercial dispensaries. By pooling resources and negotiating directly with third party cultivators for larger quantities of cannabis the clubs buying power translates into offering medicinal cannabis to its members at lower than retail prices. The cost of medicinal cannabis under regulatory schemes has proven to be out of the financial reach of many patients. In jurisdictions where this has been clearly evident, such as Canada, patients rely heavily on the ability to grow their own cannabis under PPL's or with the assistance of designated growers via Compassion Clubs. Of 38,000 licences issued by Health Canada in 2013, 28,000 were for PPL.[542]

5. Compassion Clubs also operate Medicinal Cannabis Clinics, and other ancillary complementary therapies to their members at competitive prices.

6. Compassion Clubs or Co-operatives are essentially a culmination of a number of the following elements within the medicinal cannabis scheme which have been outlined and advocated in this submission:

    - cultivation (via third party DPL) incorporating a Medicinal Cannabis Dispensary model; or alternatively

- a cultivation, Medicinal Cannabis Dispensary and Medicinal Cannabis Clinic model.

As such, the Compassion Club addresses a number of patient and community needs in an expedient and cost effective manner. It is a comprehensive model and with its various elements operating from one location, it makes for an easier and more attractive model to regulate from a compliance perspective.

7. Compassion Clubs are currently employed in Canadian provinces and in 23 states in the USA. In Canada, they are not a part of the regulated Canadian medicinal cannabis program. The Canadian model arose from patient necessity in response to the failings and deficits in the statutory model offered to Canadian patients by the Canadian Government. Despite the fact that they operate outside of the statutory scheme, they are recognized by the Canadian Judicial system as providing an essential community service.

8. Despite suggestions that these organizations may operate as a front for organized crime and diversion to the illicit market, there is little evidence to support these claims. In fact in Canada, where they operate outside the statutory framework established for their medicinal cannabis scheme, police organizations recognize this fact and tolerate the operation of both Compassion Clubs /Medicinal Cannabis Dispensaries. These organisations, which were established in recognition of the failings of the current health system, continue to operate under the threat of prosecution because they recognise and serve a legitimate compassionate need and uphold fundamental human rights. Open civil disobedience in such a transparent manner is not consistent with the general modus operandi of organised crime. Most of the Compassion Clubs and Medicinal Cannabis Dispensaries currently in operation in Canada, do not support organized crime, the re-sale of cannabis to non-medical users or recreational cannabis use.[543]

9. The British Columbia Compassion Club Society (''the Society") is a very successful illustration of Compassion Club model. Operating since 1997 it is an incorporated non for profit organization under the British Columbia Society Act 1996 with a constitution, bylaws and Board of Directors, that includes Associate Professor of Psychiatry, Lester Grinspoon[544]Patient's who are members of the Society benefit by having a third party grow cannabis under strict organically grown conditions. The Society enters into exclusive supply contracts with designated growers to provide low cost cannabis and/ or cannabis that is donated to the Society.[545]

10. Designated growers who supply the Society are carefully screened and selected on the basis of a number of criteria.[546]As a part of their exclusive arrangement with the Society, the cultivators must meet the Society's quality control standards with regard to the use of agricultural products in crop production, as well as cultivation, curing and storage techniques.[547]The Society's preference for organically produced cannabis, reflects the desires of its membership base that would grow organic cannabis under a PPL, if they were in a position to do so. Cannabis that is not organically grown is processed and cured to ensure that it meets their high quality assurance standards and laboratory testing before being offered for sale.[548] Access to the cultivation site is provide to the Society's staff to carry out inspections that look for:

    - cleanliness;
    - safety of the production site;

- plant numbers and that scale of the operation does not exceed the amount agreed to be supplied to the Society;
- health of plants;
- security of the property/growing facility;
- air quality; and / or
- evidence of mould, mildew, fungi or other contaminants.[549]

11. Failure to comply with the quality assurance standards set by the Society, especially regarding the health of plants and presence of mould, mildew and or fungi, gives the Society the right to terminate an agreement with a designated grower.[550]

12. Upon delivery of a yield from a crop grown for and on behalf of the Society by a designated grower, the crop yields are again carefully examined for mould, mildew and fungi and samples are sent to laboratories for microbiology testing, chemical and other analysis prior to being supplied to the Society members.[551]

13. Operating in this manner, the Society can provide a wide variety of high quality cannabis strains to its members at costs below those offered by licensed Canadian commercial producers.

14. In addition to a dispensary the Society also operates as a Medicinal Cannabis Clinic. It also offers a number of other complementary therapeutic modalities to medicinal cannabis patient members that it can provide below customary retail prices. For many financially disadvantaged patients, this provides access to healing modalities that they would otherwise be denied. In turn, this adds to their quality of life. Compassion Clubs successfully demonstrate that relief from suffering and an improved quality of life, need not be a privilege limited to the affluent.

15. This submission favours the adoption of the British Columbia Compassion Society Club model and would like to se it operating in Victorian under a proposed medicinal cannabis scheme.

16. A Compassion Club wishing to operate in Victoria could apply to the relevant Victorian Government agency or department for Commonwealth and Victorian license, which could be issued simultaneously in the form(s) of:

- an Authority to Possess License ("APL") for a Compassion Club;
- a Commercial Manufacturing License ("CML") to manufacture cannabis products;
- a Medicinal Cannabis Dispensary License ("DL"); and
- DPL (A)'s with each new member, to appoint third party cultivators holding a DPL.

17. A Compassion Club could be required to apply to the relevant Victorian Government agency or department for a DPL (A) for each new member of its club. These would provide the club with the authority to engage a number of third parties holding DPLs to cultivate the required quantity of cannabis on behalf of the club and each member holding a DPL (A). The quantity of cannabis that the club might be able to arrange to be grown in such circumstances would be limited to the quantity identified by the members DPL (A), as indicated on the members Medicinal Cannabis Card.

18. The requirements of a Compassion Club associated with making an application for a DPL (A) are set out at "Designated Production Licenses and Third Party Producers." of this submission.

19. The quantities of cannabis a Compassion Club could have cultivated by a third party holding a DPL and which may be stored at the club at any one time are referred to at "Designated Production Licenses and Third Party Producers." of this submission.

20. Compassion Club in Victoria would, in accordance with a valid manufacturing and dispensing license, manufacture and dispense medicinal cannabis and cannabis products produced by the club's contracted DPL's and suppliers, to its members in accordance with its constitution and membership regulations.

21. Requirements and relevant considerations associated with licensing, licensing renewal and operating a Medicinal Cannabis Dispensary as a part of a Compassion Club, are set out at "Processing and Distribution: Dispensaries" in this submission.

22. Requirements and considerations relevant to licensing, licensing renewal and operating a Medicinal Cannabis Clinic as a part of a Compassion Club are set out at "Processing and Distribution: Medicinal Cannabis Clinics" in this submission.

23. Requirements and considerations relevant to licensing, licensing renewal and operating manufacturing activities as a part of the clubs operations, are set out at "Manufacturing Cannabis Products'' (below) in this submission.

24. In addition to the aforementioned, a Compassion Club could also be required for the purposes of its licensing operations to:

    a. attend to mandatory batch testing from a number of different areas of a number of flowers from a plant(s) of a specific crop batch, undertaken through specific accredited medicinal cannabis laboratories for:

        - flower appearance (rating);
        - cannabinoid and terpene profile expressed as percentage of total weight;
        - cannabinoid and terpene profiles expressed in mg per gram;
        - absence of hairs, insects, bacteria, fungi, pesticides, chemicals, heavy metals, mould or other contaminants;
        - any other contaminants;

    b. maintain a register with the details of all members of the club including details of their DPL (A) and Medicinal Cannabis Card details together with details of the club's DPL (A) issued in respect of the new member;

    c. maintain a register with the details of all DPL holders engaged by the club;

    d. maintain a separate register for each DPL holder engaged by the club for the purposes of recording the following information:

        (i) details of the member (including details of their [DPL (A)] which resulted in engaging a DPL by the club to cultivate a crop up to the limit specified under the members DPL (A);

(ii) the date that member joined the club, together with the date of the club's application and the date of issue of the clubs DPL (A) associated to that member;

(iii) the date of the club's instruction to the holder of the DPL to cultivate the quantity of cannabis associated with the members DPL (A);

(iv) the date of a notice issued from the DPL and / or the relevant Victorian Government agency or department or Local Municipal Council regarding anticipated excess cannabis yield over state quota, together with the date received and a copy of such notice;

(v) the date of receipt of a cannabis crop yielded under that arrangement together with the quantity received, including any unexpected excess cannabis yielded above the permitted members storage quota, to be identified separately, with all quantities clearly identified and specified;

(vi) reference to and a copy of accredited laboratory reports and on batch testing in relation to the specific crop associated with the specific DPL (A) club member, cultivated under a DPL and received by the club;

(vii) date(s) when the crop yield and any unexpected crop yield over a members permitted storage quota was passed across to the club's dispensary operations;

(viii) quality assurance standards and other key performance indicators required to be met by the DPL under contractual obligations;

(ix) local municipal council inspection reports, as well as club's reports on site inspection and or similar periodic reports on DPLs compliance with the matters set out at (viii);

(x) a copy of the horticultural, cultivation and curing records kept by the DPL in the form of a register relevant to the crop grown for and on behalf of the club;

e) maintain a register with respect to manufacturing processes; [See: "Processing and Distribution: Manufacturing Cannabis Products" in this submission.]

f) ensure compliance with record keeping and auditing process regulations made in accordance with S 23 Narcotic Drugs Act 1967 (Cth) by submitting records, reports and returns (as required) to the Commonwealth Secretary regarding manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;

g) ensure current and relevant insurance policies are held, including public and product liability insurance.

25. Under the model promoted, individuals holding DPL licenses would be limited to cultivating medicinal cannabis for up to 5 patients/members only**.** Although the cannabis cultivated using a members specific DPL (A) would be for the benefit of all club members, linking each members DPL (A) to a DPL via the clubs records in the manner set out above, would assist in maintaining high quality assurance standards and provide quick identification for product recall purposes. Such a process would also assist with auditing and regulatory compliance associated with both a Compassion Club and individuals holding DPL's under the scheme.

26. Each batch received from a DPL and recorded in the above manner, should also be capable of being identified in the clubs dispensary, for quality assurance and risk management purposes i.e. diversion prevention and product recall purposes.

27. A patient, parent or guardian holding a Medicinal Cannabis Card in the form of a DPL (A) and who is a member of a Compassion Club would:

(i) be permitted to have prescriptions up to the percentage of their Maximum Total Daily Dose over the prescription period and up to their permitted storage quota as stated under the terms of their DPL (A);

(ii) In paying a membership fee to the club would not pay the DPL third party grower contracted with by the club. The reasonable costs associated with cultivation being paid for by the Compassion Club.

28. The British Columbia Compassion Club Society in association with the Vancouver Island Compassion Society has created and published professional guidelines for the creation and operation of community based Compassion Clubs and dispensaries, which are adhered to by many of 103 such models currently operating across Canada. Its guidelines are comprehensive and impressive, addressing standard quality control and regulatory compliance issues commonly associated with similar regulatory models.

29. The Commission is referred to ""Capler, R and lucas, P. "Guidelines for the Community Based Distribution of Medicinal Cannabis." British Columbia Compassion Club Society and Vancouver Island Compassion Society. 2006. ("Guidelines") **[See: Annexure 3]**

30. Revocation of a Compassion Club License could occur where:

- the license holder requests the revocation;
- the license holder was not eligible to hold a license;
- the license was obtained on false or misleading information;
- the license holder failed to obtain or retain other relevant licenses (if any) under the scheme;
- the license holder's acts or omissions related to the operation of a Medicinal Cannabis Dispensary triggered a revocation of that license;
- an unreasonable percentage of its membership base were found to hold invalid DPL(A)'s;
- has breached one or more of the conditions referred to at paragraphs 24 and 26 without reasonable cause;

31. Revocation of a Compassion Club license would be subject to and would not take place unless the relevant Victorian Government agency or department(s):

- issued written notice to the license holder setting out the reasons for the proposed revocation; and

- the license holder has been given the opportunity to be heard through an appropriate review or appeal's process;

32. Where a license is revoked and the holder of the license does not intend to contest the matter via an appropriate review or appeals process, the holder of the license would return the relevant license within 30 days of receiving the notice referred to at paragraph 31 to the relevant Victorian Department agency or department(s) responsible for the administration of the scheme or alternatively;

33. Where a license holder wishes to challenge the reasons for the license revocation, forfeiture of the license would take place at the conclusion of any review or appeal process where the outcome did not favour the license holder. It is important that the license holder have access to medicine until all claims leading to the revocation of the license have been heard and definitively determined. Anything short of such could deny patients access to medicine and amount to a breach of a patients fundamental Human Rights.

MANUFACTURING CANNABIS PRODUCTS

1. The model proposed by this submission for a medicinal cannabis scheme for Victoria, recognises the importance of establishing a lawful supply of and access to medicinal cannabis and medicinal cannabis produces.

2. Access requires that a patient be able to obtain medication that is appropriate for the particular individual's needs. This submission consequently supports the supply of all forms of medicinal cannabis and medicinal cannabis products.

3. Cannabis concentrates, extracts, tinctures, topical creams and edible cannabis products are popular and important cannabis therapeutics amongst patients in Australia and overseas. Within the operation of any proposed scheme provision must be made for:

    - a variety of medicinal cannabis products in order to meet a variety of individual patient therapeutic needs;

    - products being made available at compassionate retail prices; and

    - the licensed manufacture and distribution of these products being made available to patients, parents, guardians and carers via licensed medicinal dispensaries.

4. Cannabis products could be manufactured and / or supplied for sale by applying to the relevant Victorian Government agency or department responsible for administering the scheme for a "Commercial Manufacturing License" ("CML") which could be operated:

    i. as a stand alone manufacturing business model; or

    ii. as a manufacturing operation with a dispensary to supply products authorised under prescription; or

    iii. as a manufacturing operation with a cultivation license to produce cannabis for manufacturing such products; or

    iv. as a manufacturing operation with a cultivation license to produce cannabis for manufacturing such products together with a dispensary to supply products authorised under prescription.

5. A CML would incorporate relevant Commonwealth and Victorian authorities and licenses required to possess, use, process, manufacture, package, supply and sell cannabis and cannabis products.

6. All manufacturers of edible products could:

    a. obtain additional required licenses (if any) in regard to the handling and sale of food under relevant Victorian laws and would;

b. comply with laws associated with the manufacture, handling and supply of food in Victoria.

All manufacturers of cannabis concentrates, extracts topical creams or similar products could:

i. obtain any relevant licenses to attend to the same and customarily associated with the manufacture of non cannabis products and would;

ii. comply with any relevant Victorian laws.

7. With the exception of concentrates involving butane extraction (which can be dangerous) and / or other methods that might call for special licensing requirements, cannabis extracts, tinctures and edibles manufactured for retail sales purposes, could and should be readily made without any special licensing requirement where considered in consultation with and / or under the supervision of professionals including a:

a. pharmacist
b. herbalist
c. naturopath

8. End products could be subjected to the same mandatory batch testing requirements applicable to commercial cultivation and dispensary operations as previously discussed in this submission.

9. Manufacturers, particularly those who:

a. operates a stand alone manufacturing business; or

b. operates a cultivation license and produces cannabis to manufacture medicinal cannabis products

would be required to take regular delivery of quantities of cannabis from a commercial cultivator sufficient for their manufacturing purposes and:

i. make products using cannabis supplied either directly or by first extracting the plants oil;

ii. package and label those products in accordance with regulations under the scheme;

iii. securely deliver these products strictly to licensed Medicinal Cannabis Dispensaries operating within the scheme.

10. Proposals outlined at “Cultivation: Commercial Licensed Producers”; “Processing and Distribution: Dispensaries’’ and “Processing and Distribution: Compassion Clubs & Co-Operatives” in this submission and particularly those relevant to:

- keeping secure and separate registers, including registers of: Commercial Suppliers of Cannabis, Sales & Distributions, Substandard and Returned Goods, Quality Assurance Standards and Risk Management, together with any other relevant registers previously discussed in relation to commercial cultivation, Medicinal Cannabis Dispensaries and Compassion Clubs that would assist inventory tracking, quality control and risk management purposes i.e. product diversion and recall;

- daily inventory and stock reconciliation;

- periodic auditing and requirements associated in preparation for the same;

- general inventory management applicable to commercial producers and or Medicinal Cannabis Dispensaries;

- quality assurance and risk management measure, applicable to commercial producers and /or Medicinal Cannabis Dispensaries

could be transferred to these and other identified manufacturing models under a proposed scheme.

11. The risk management and quality assurance strategies referred to would be employed to ensure that cannabis and cannabis goods received, could be tracked from point of receipt to point of manufacture and supply to third party Medicinal Cannabis Dispensaries where they will be supplied under prescription.

12. In addition to the aforementioned, details such as:

    a. descriptive and identifying details of cannabis and cannabis products received;

    b. date, weight, moisture content of cannabis and cannabis products received;

    c. details of the supplier of cannabis and / or cannabis;

    d. date of receipt of delivery from commercial producer or manufacture of specific cannabis strains and cannabis products;

    e. batch and /or registered supply number on the labelling on tamper proof commercial producers bags or sealed packaging relating to cannabis and /or cannabis goods received;

    f. dates of processing and best before/ expiry dates stated on labelling on tamper proof / tamper evident commercial producers bags and /or cannabis product packaging;

    g. cannabinoid and terpene profile and potency relevant to the cannabis supplied according to labelling on tamper proof /tamper evident commercial producers' bags and or packaging of cannabis products;

    h. laboratory report confirming same and date thereof;

i. quantity of cannabis and / or cannabis products from a commercial producer contained in each tamper proof commercial producers bags (as recorded on such a bags label) and the quantity determined after the contents of such a bag are weighed by the manufacturer on pharmacy, industrial or similar grade calibrated scales. Results from calculations of moisture loss would be recorded for inventory reconciliation purposes. The date of such activities would also be recorded;

j. ensuring above details are tracked to and cross referenced with cannabis and cannabis goods produced by the manufacturers for storage into sterile hygienic inventory areas and vessels and that quantities used in manufacturing taken from such locations and vessels are recorded and tracked at each step in the creation of each batch of product in the manufacturing process;

k. recording returns for substandard cannabis and / or cannabis products and or damaged bags and or packaging which could include details to: identify the cannabis and cannabis products in question i.e.: batch and / or registered supply number, commercial supplier and / or manufacturers details, quantity received, date received, description of fault, date of notification to the commercial producer/manufacturer, date collected from the commercial producer/manufacturer and receipt of return received from the commercial producer/manufacturer;

l. compliance with record keeping and auditing processes regulations in accordance with S 23 Narcotic Drugs Act 1967 (Cth) with the submission of records, reports and returns (as required) to be provided to the Commonwealth Secretary regarding manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;

m. manufacturing small, distinct, severable serving portions for edible products with standardized cannabinoid content batch to batch;

n. clear labelling of edible products that in addition to any information generally required to identify food constituents, would also identify the cannabinoid and terpene profile used in such products; the potency of such products referencing the total THC content and ratio to other cannabinoids in the product, together with an accurate measurement of such in each severable serving portion; and

o. non descript, discrete packaging that clearly distinguishes all cannabis products from any other similar non medicinal retail products;

could be recorded and attend too by manufacturing operations.

13. Risk management processes of the nature discussed in this submission would reduce the possibility of cannabis and/ or cannabis products being diverted to the illicit market.

14. The decision whether to manufacture separate from or as an extension to, cultivation and or medicinal dispensary operations, should be left to discretion of potential business operators.

15. If Victoria is to provide quality medicinal cannabis products, it must provide options that will attract the right business operators with the right skill sets and financial capacities. Allowing various models will achieve such outcomes as well as providing a wide variety of quality cannabis products that will be required to meet the divergent medicinal needs of patients being treated under any proposed scheme.

16. Offering different manufacturing models operating under appropriate licenses and within a regulatory framework of a proposed medicinal cannabis scheme would:

- allow for specialisation according to skill sets and result in higher quality products;
- recognise divergent financial capacities associated with the different manufacturing models, therefore providing realistic financially sustainable business operations that could supply medicinal cannabis products over the long term; and
- provide a divergent range of specialised higher quality products at competitive compassionate pricing.

17. Licensing applications, renewal and operation of licensing requirements for medicinal cannabis manufacturers could include many of the same consideration referred to and previously discussed in this submission in relation to Commercial Production Licenses and Medicinal Cannabis Dispensaries. In addition to such, the following might also be considered:

- suitability and security associated with the manufacturing premises;
- compliance with the Narcotic Drugs Act 1967 (Cth) regarding manufacturing premises unless otherwise modified by the Commonwealth for the operation of a Victorian medicinal cannabis scheme;
- location of the manufacturing premises;
- arrangements for the secure return of substandard cannabis and damaged product and / or packaging to commercial producers or otherwise in accordance with regulations relating to the same, including those made under the Narcotic Drugs Act 1967 (Cth), unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;
- record keeping and auditing processes to comply with S 23 Narcotic Drugs Act 1967 (Cth) with the submission of such records /reports and returns (as required) to be provided to the Commonwealth Secretary with respect to manufacture, acquisition, disposal and other dealings with inventory, unless otherwise modified for the operation of a Victorian medicinal cannabis scheme;
- arrangements for the secure delivery of cannabis products to Medicinal Cannabis Dispensaries;
- the skill set and experience of the applicant with respect to the food and / or commercial manufacturing and any relevant pre existing licenses held under relevant legislation and compliance with the same;

- the knowledge of the applicant and applicants staff regarding cannabis and cannabis manufactured products and the manufacture and supply of the same;

- the business model's capacity to produce cannabis products at compassionate prices; and

- holding relevant public and product liability insurance.

18, For considerations relevant to the revocation of manufacturing licenses, the Commission is referred to the considerations previously discussed in this submission in relation to Commercial Production Licenses and Medicinal Cannabis Dispensaries.

PART NINE

OPERATION AND IMPLEMENTATION OF A LEGAL AMNESTY

1. It is acknowledged that the Victorian Government has stated its intention to introduce legislation to the Victorian Parliament to establish a medicinal cannabis scheme before the end of 2015.

2. However the proposed model, the costs and infra structure associated with such a scheme remain unknown. Whilst legislation for the purposes of a scheme may come into operation by the end of 2015, it may be 12 months or more, before such a scheme becomes operational.

3. It is submitted that Victorians with terminal and other life threatening illness cannot wait for the introduction of a possible scheme. These Victorians are being placed in the unacceptable situation of having to choose between the fundamental human rights of health, life and liberty. Many Victorians are choosing health and life over the potential loss of liberty that comes from the possible incarceration associated with cultivation and use of cannabis for medicinal purposes. Whilst the Victorian Judiciary might be sympathetic to the plight of such Victorians there are no guarantees that patients and especially their medicinal cannabis suppliers, will be met with such. Further, the stress and costs associated with legal process are taxing for most healthy Victorians. It is shameful that seriously ill Victorians and their families or loved ones, must face this burden with its attendant present uncertainties.

4. It is submitted that the threat of prosecution must be removed from patients, their care providers and compassionate cannabis cultivators. It has been suggested that legislation (with the co-operation of the Federal Government) containing a sunset provision could be introduced to offer such individuals exemption from prosecution. It is understood, that interim legislative measures of a similar nature, were introduced in jurisdictions in the USA before their medicinal cannabis schemes became operational. Attendance to such a measure would demonstrate to Victorian's the bona fide intention on the part of the Victorian government towards the full implementation of a medicinal cannabis scheme.

5. However this measure may also take time and become bogged down in the politics of medicinal cannabis.

6. It is submitted, that in lieu of the aforementioned proposal, the Victorian Government under an arrangement with the Commonwealth government could introduce an amnesty for Victorians, to take effect forthwith. This could be facilitated by requiring:

   - a letter from a medical practitioner stating that:

     - the patient's medical history has been fully reviewed;
     - the patient has undergone a full medical examination;
     - the patient has been advised and accepts the risks associated with the use of cannabis; and the patient intends to use cannabis for medicinal purposes;

   - a statutory declaration from the patient, parent or guardian stating and providing (where applicable):

- the patient details;
- the patients parents, guardian or care providers details;
- that the patient is cultivating their own cannabis; or
- the patient has appointed a third party to cultivate cannabis or;
- the patient has appointed a third party to cultivate and supply medicinal cannabis;
- third party cultivators and/or suppliers details;
- the location of the cultivation site(s);
- the approximate number of flowering plants to be harvested;
- whether the cultivation is indoors or outdoors;
- where cultivation is indoors and outdoors: the approximate number of flowering plants to be grown indoors and the approximate number of flowering plants being grown outdoors,
- the approximate number of trailing plants required, in order to compensate for male plants and/or plant attrition;
- the location at which cannabis is to be stored;
- the location(s) at which cannabis is to be used or administered i.e. home, school, or hospital etc.;
- the details of any third parties administering medicinal cannabis to the patient, including where administration is to commonly take place;
- that cannabis is to be cultivated and used solely for medicinal purposes and strictly for the use of the patient.

➢ a statutory declaration from the third party cultivator and or supplier stating and identifying (where applicable):

- the third party cultivator and/or suppliers details
- the patient and patients details;
- the patients parent, guardian or care providers details;
- that the third party is to cultivate and or supply medicinal cannabis to the patient;
- the location of the cultivation site(s);
- the proposed number of flowering plants to be harvested;
- whether the cultivation is indoors or outdoors;
- where cultivation is indoors and outdoors: the approximate number of flowering plants to be grown indoors and the approximate number of flowering plants to be grown outdoors;
- the approximate number of trailing plants to compensate for male plants and plant attrition;
- the location at which the cannabis is to be stored prior and up to the point of delivery to the patient, parent, guardian or care provider;
- that cannabis is to be cultivated and/ or supplied solely for the benefit of the patient identified and strictly for medicinal purposes only.

- the medical practitioners letter and statutory declarations would be lodged with the Victorian Department of Health and Human Services and the Victorian Justice Department;

- A letter from the Department of Justice sent to:

    - the Department of Health and Human Services;

    - the patient, parent, guardian or care provider's identified in the patients statutory declaration; and to

    - the medicinal cannabis cultivator and /or supplier;

  acknowledging receipt of the medical practitioners letter and statutory declarations, could state clearly, that the parties have been provided an amnesty from prosecution;

- The letter from the Department of Justice could be relied upon by the relevant parties associated with the cultivation, harvest, supply and use of medicinal cannabis.

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[1] The Australian Marijuana Grower's Guide. Otter Publications. Redfern. NSW. (1996)

[2] Charlier, P. Hemp in British and Australian Colonial History. See:http://www.athertontablelandnetguide.com/history/hemp/

[3] The Australian Marijuana Grower's Guide. Otter Publications. Redfern. NSW. (1996)

[4] Ibid.

[5] Jiggens, J. "The Origins of Marijuana Prohibition in Australia", Sticky Point Magazine. Issue 05 (2008); Cartwright, L. 'Marihuana', Current Affairs Bulletin. (1983); Vol. 59, No. 10, pp.19-31.

[6] Robert Kendell: "Cannabis condemned: the proscription of Indian Hemp Addiction". Addiction. (2003): Vol. 98. pp 143-151, At p. 98 it stated that the Egyptian delegation to the UN engaging in the treaty process contended that cannabis was as dangerous as opium and should therefore be included and subject to the same international controls. Although this was supported by other countries, formal evidence of the matter was never produced and delegates were never briefed about cannabis and or it's alleged dangers.

[7] UNODC. World Drug Report. 2010. United Nations Publication. p. 198.

[8] "Australia Has Highest Use of Cannabis Users in the World". Daily Telegraph. Jan 2012.

[9] National Drug Strategy Household Survey Key Findings. (2013 released Nov 2104) ISSN 1442-7230; ISBN 978-1-74249-665-8; Cat. no. PHE 183; 161.

[10] Copeland, J. "Torch The Joint" ABC. (April 29th, 2008).

[11] Ibid.

[12] National Drug Strategy Household Survey Key Findings. Ibid.

[13] Armentano, P. ''Recent Research on Medical Marijuana: Emerging Clinical Applications for Cannabis and Cannabinoids. A Review of the Recent Scientific Literature 2000-2103''. NORML Foundation. (Jan 2014) Washington, D.C.

[14] See: The Need for a Medicinal Cannabis System in Victoria of this submission at paragraph 17.

[15] MCUA is an online advocacy and educational group founded in June 2014 which is currently supported by an estimated 6,500 people.

[16] Preamble, Art 1(2); Art 4; Art 5; Art 9(4); Art 19(1)(a); Art 21 (4)(b)(ii); Art 28; Art 30; Art 30(1)(b)(c) & 30 (2)(b)(i).

[17] Ibid. Preamble.

[18] Art 9 (4); Art 19 (1)(a); Art 21 (4)(b)(ii); Art 28; Art 30; Art 30(1)(b)(c) & 30 (2)(b)(i)

[19] The United Nations Single Convention on Narcotic Drugs (1961); The Convention on Psychotropic Substances (1971); United Nations Convention Against Illicit Traffic of Narcotic Drugs and Psychotropic Substances(1988).

[20] Robert Kendell: "Cannabis condemned: the proscription of Indian Hemp Addiction". Addiction. (2003); Vol. 98. Issue 2.

[21] See: Abbott Products Inc. Marinol Product Monograph.2010: The estimated lethal dose of THC required to be administered intravenously at 2100 mg/70 kg. At these levels it is unsurprising to learn that ''there has been no documented evidence of death exclusively attributable to cannabis overdose to date." Information for Healthcare Professionals: Cannabis (marihuana, marijuana) and the cannabinoids." Health Canada. (2013). P 94.

[22] National Drug Strategy Household Survey Key Findings 2013 Ibid.

[23] Ibid. Table. 5.5

[24] National Drug Strategy Household Survey Key Findings 2013. Ibid.

[25] National Drugs Strategy Household Survey Key Findings 2013. Ibid. See Table 5.13

[26] Ibid.

[27] Davey, M. "Prescription drugs involved in 82% of overdose deaths, Victoria Coroner says". The Guardian. (March 2015).

[28] Ibid.

[29] Corderoy, A. "Pain Killer Deaths on the Rise". The Sydney Morning Herald. (Oct 2012).

[30] Corderoy, A. "Medicinal cannabis: study finds Australians suffering chronic pain get more relief from cannabis than Conventional medicines". The Sydney Morning Herald. (Jan 2015); Degenhardt, L., Lintzeris, N., Campbell, G., Bruno, R., Cohen, M., Farrell, M., Hall, W.D., "Experience of adjunctive cannabis use for

chronic non-cancer pain: Findings from the Pain and Opioids IN Treatment (POINT) study". Drug and Alcohol Dependence. (Feb 2015); Vol.147, p. 144-150.

[31] Ware, M., Adams, H. and Guy, G. "The Medicinal use of cannabis in the UK: results of a nationwide survey''. International Journal of Clinical Practice. (2005); 59(3);291-295.

[32] Copeland, J. Ibid.

[33] Copeland, J., Davey, M. "Prescription drugs involved in 82% of overdose deaths, Victoria Coroner says'' Ibid.

[34] Mardones,, V. "Herbal Cannabis as Medicine: A bio cultural analysis." University of Kent-Cantebury. (Sept 2011).

[35] Ibid.

[36] Swift, W., Gates, P & Dillion, P. "Survey of Australians using cannabis for medicinal purposes". Harm Reduction Journal. (2005); 2:18 .

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[399] Carter, G.T. See: Fn. 388

[400] Gordon M. CEO of Aunt Zelda's Pediatric Cancer and Cannabis Center USA paper presented at the Inaugural Medicinal Cannabis Symposium. United in Compassion Tamworth NSW (Nov 21, 2014).

[401] The current cross party federal bill No 44 -Regulator of Medicinal Cannabis, is currently before the Senate. See: http://www.aph.gov.au/Parliamentary_Business/Bills_LEGislation/Bills_Search_Results/Result?bId=s987

[402] Preamble, Art 1(2); Art 4; Art 5; Art 9(4); Art 19(1)(a); Art 21 (4)(b)(ii); Art 28; Art 30; Art 30(1)(b)(c) & 30 (2)(b)(i).

[403] Ibid. Art 1. Definitions.

[404] As reflected in the current cross party federal bill No 44 -Regulator of Medicinal Cannabis, is currently before the Senate. See: http://www.aph.gov.au/Parliamentary_Business/Bills_LEGislation/Bills_Search_Results/Result?bId=s987

[405] United Nations Single Convention on Narcotic Drugs (1961) Art. 23 & 28

[406] The concerns addressed by FSANZ were not associated with cannabis as food but rather the degree to which it might interfere with roadside drug testing.

[407] The current cross party Regulator of Medicinal Cannabis federal bill is believed to have been formulated in recognition of the fact that cannabis cannot be regulated under the existing national TGA framework.

[408] The Victorian State Government should go further and request the Commonwealth to amend this legislation to exempt participants from prosecution, rather than to provide them with a defence in the event of prosecution.

[409] International Convention on Economic Social and Cultural Rights [1976]

[410] ACSGH (2008) Australian Charter of Healthcare Rights. Sydney: Australian Commission on Safety and Quality in Health Care; See: http://health.vic.gov.au/patientcharter/healthcare-rights-inVictoria/index.htm

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[413] Preamble, Art 1(2); Art 4; Art 5; Art 9(4); Art 19(1)(a); Art 21 (4)(b)(ii); Art 28; Art 30; Art 30(1)(b)(c) & 30 (2)(b)(i).

[414] UN Single Convention on Narcotic Drugs 1961. Preamble

[415] Ibid.

[416] Patients can determine from the smell of the cannabis (due to terpene content) as to whether the strain will be beneficial based on their past experience and or use. A bud that was strong in pine notes for example, may not be agreeable to the patient/patient's condition based on their past use.

[417] This was costly and caused lengthy delays in being able to access cannabis and obtain relief from chronic conditions. It was unsuitable for terminal patients and or for those who required immediate symptom relief. It was an unrealistic option when patients could access cannabis from the illicit market without the attendant stress and costs.

[418] Canadians for Safe Access; BC Compassion Club Society and the Victoria Island Compassion Society. Lucas P., Black, H. and Capler, R. "A Roadmap to Compassion: The Implementation of a Working Medicinal Cannabis Program in Canada.'' (2004).

[419] Markowitz, E: "How to Open a Medicinal Marijuana Dispensary'' See: http://www.inc.com/zoe-henry/how online-flower-companies-prepare-for-mother-s-day.html

[420] Marihuana Medical Access Regulations SOR/2001-227 made under the Canadian Controlled Drugs and Substances Act

[421] Allard –v- R Fed. Crt .B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005 and Affidavit of Prof Mikos. See: at http://www.johnconroy.com/mmar.htm

[422] Carter, G.T., Weydt, P., Kyashna-Tocha, M., Abrams, D. "Medicinal cannabis: Rational guidelines for dosing." Drugs (2004); 7(5): 464-470.

[423] Marihuana Medical Access Regulations SOR/2001-227 made under the Canadian Controlled Drugs and Substances Act See: Reg 30 & 31

[424] Ibid.

[425] Ibid Reg 65-57

[426] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. (April 30 2005). Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005. See: http://www.johnconroy.com/mmar.htm

[427] The Dignified Access Initiative – Proposal to Implement a Medicinal Cannabis Program for Ontario. 2015. Canadian Medicinal Cannabis Partner and the Medicinal Cannabis Patients Alliance of Canada. See: http://dignifiedaccess.mcpacanada.org

[428] Evidence of J. Shaw B.C. Compassion Club Society given and referred to in Allard –v- R Fed. Crt. B.C. Phelan J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005.

[429] ''Understanding Medicinal Cannabis – Elemental Wellness'' Steep Hill Halent Lab –'2nd Ed. (2014)

[430] Legislative Council General Purpose Standing Committee No 4. Parliament of New South Wales. The Use of Cannabis for Medicinal Purposes (2013); 71 (Recommendation 2).

[431] Drugs, Poisons and Controlled Substances Act 1981 (Vic) S. 73, 75 could be amended to exempt medicinal cannabis users from criminal prosecution.

[432] Cultivation is prohibited under the Drugs, Poisons and Controlled Substances Act 1981 (Vic) unless it is authorised by license under the Act or regulations. The Act and or regulations could be amended to allow cultivation under license. This would also provide Victorians with a defence under the Crimes Code Act 1995 (Cth). Cultivation is not prohibited under the federal act, if it is otherwise authorised under a law of a state or territory.

[433] Amend Therapeutic Goods Act 2010 (Vic). However it is suggested that this act does not apply to the regulation of cannabis . However, individuals would still be required to apply to the Commonwealth for a manufacturing license under the provisions of the Narcotic Drugs Act 1967 (Cth). It is uncertain as to whether the Act binds the Victorian State Government. However, the Victorian State Government might request the Commonwealth to amend the Narcotics Drugs Act 1967 (Cth) to exempt Victorians participating in a medicinal cannabis scheme from being required to apply for and or hold manufacturing licenses.

[434] For individual supply and sale, the Victorian Government could amend TGA 2010 (Vic). However it is suggested that this act does not apply to the regulation of Cannabis.

[435] See Fn: 433 above

[436] Canadians for Safe Access. BC Compassion Club Society and the Victoria Island Compassion Society. Lucas, P; Black, H and Capler, R. R "A Road Map to Compassion . The Implementation of a Working Medicinal Cannabis Program in Canada". 2004.

[437] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005. and Affidavit of Sandvos, C. at http://www.johnconroy.com/mmar.htm

[438] Allard –v- R Fed. Crt. B..C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005, and Affidavit of Rocht, J., Health Canada. See: http://www.johnconroy.com/mmar.htm

[439] "The State of Legal Marijuana Markets "– Third Edition', Arcview Group. 2015. See http://www.arcviewmarketresearch.com/order/state-of-the-legal-marijuana-markets-2nd-edition

[440] Ibid.

[441] Ibid.

[442] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005

[443] Ibid.

[444] Allard –v- R Fed. Crt. B..C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005, and Affidavit of Rocht, J., Health Canada. See

[445] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005.

[446] Ibid.

[447] Illicit Drug Data Report 2012-13. Australian Crimes Commission. (April 2014). ISSN 2202-3925

[448] **Alexander Harriet, "Online drug sales boom" The Age. Fairfax Media. June, 8, 2015.**

[449] See: para 27 in "The Need for a Medicinal Cannabis Scheme in Victoria." of this submission.

[450] Allard –v- R Fed. Crt .B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005 and Affidavit of Prof Mikos. See: at http://www.johnconroy.com/mmar.htm

[451] Russ, B. The Disaster Of CBD-Only 'Medical Marijuana' Legislation. The Weed Blog. See: http://www.theweedblog.com/the-disaster-of-cbd-only-medical-marijuana-legislation/

[452] RIbinski, G. "Why CBD is Not Enough: The Entourage Effect." www.whaxy.com

[452] Tori La Chappel CBD Only Bills: A Whole Plant Cannabis Activist Testifies in Wisconsin. March 2014. See: http://www.ladybud.com/2014/03/19/cbd-bills-a-whole-plant-cannabis-advocate-testifies-in-wisconsin/

[453] See: The Marijuana Policy Project USA http://www.mpp.org. Also: RIbinski, G. "Why CBD is Not Enough: The Entourage Effect." www.whaxy.com

[454] Tori La Chappel CBD Only Bills: A Whole Plant Cannabis Activist Testifies in Wisconsin. March 2014. See: http://www.ladybud.com/2014/03/19/cbd-bills-a-whole-plant-cannabis-advocate-testifies-in-wisconsin/

[455] Waltz, V. "A Limited Amount of "Caring": Parents and Advocates React to Realm of Caring's Federal CBD-Only Bill'' 2014.See: www.ladybud.com

[456] Ibid.

[457] Ibid

[458] Hornby, A.P. "Standardized Cannabis and Pain Management." Hedron Analytical Inc. Canada. http://cdn.intechopen.com/pdfs-wm/32438.pdf

[459] See: The Marijuana Policy Project USA http://www.mpp.org. Also: RIbinski, G. "Why CBD is Not Enough: The Entourage Effect." www.whaxy.com.

[460] See: Affidavit evidence and expert report of Dr Pate at http://www.johnconroy.com/mmar.htm in Allard –v- R Fed. Crt. B.C, April 30, 2025 before Phelan, J .and referred to in Arguments Summation. Transcript. See: Conroy, J. Q.C. for the Plaintiffs at p 2005.

[461] bid

[462] Ibid

[463] Ibid

[464] Medical marijuana in a time of prohibition", Lester Grinspoon, International Journal of Drug Policy, 10 (1999) 145 – 156 at p. 147.

[465] Nicholas S. Downing, et. al. "Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents" *AMA.* 2014; 311 (4):368-377.

[466] Denis, B cites study in "FDA's 'safe and effective' drug approvals based on widely varied data, study finds'' article published Jan 2014 Washington Post USA.

[467] Grinspoon, L. "Medical marijuana in a time of prohibition". International Journal of Drug Policy, 10 (1999) 145 – 156 at p. 148.

[468] Ibid.

[469] Ibid.

[470] Ibid.

[471] Peter C. Gotzsche, founder of the Cochrane Center and in particular his most recent publication ''Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Healthcare''. Radcliffe. 2013.

[472] Canadians for Safe Access. B.C Compassion Club Society and the Victoria Island Compassion Society. Lucas, P., Black, H. and Capler, R. "A Road Map to Compassion. The Implementation of a Working Medicinal Cannabis Program in Canada.'' 2004.

[473] http://norml.org/about/intro

[474] Colorado, USA has not seen an amendment to its medical conditions / symptoms list since its inception, approximately 7 years ago.

[475] See:http://alisondb.legislature.state.al.us/ALISON/SearchableInstruments/2015RS/PrintFiles/SB326-int.pdf?hc_location=ufi

[476] Canadians for Safe Access. BC Compassion Club Society and the Victoria Island Compassion Society. Lucas, P., Black, H. and Capler, R. "A Road Map to Compassion . The Implementation of a Working Medicinal Cannabis Program in Canada". 2004.

[477] Current standard of practice under Canadian Association of Medicinal Cannabis Dispensaries Association Certification Standards for Medicinal Cannabis Dispensaries in Canada. 2013 on the basis that prescriptions may be used for up to 12 months.

[478] The state agency might enable temporary registration in the scheme upon lodgment of required documentation, to enable lawful access to cannabis medicine for patient's traveling from interstate and overseas that may be situated in Victoria for some time and who would otherwise be without access to medicine

[479] Evidence of J. Shaw B.C. Compassion Club Society given and referred to in Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p 2005.

[480] With appropriate amendments to the Drug Poisons and Controlled Substances Act 1981 (Vic) to allow for such parties to prescribe under a medicinal cannabis scheme

[481] At times of stress or additional illness, which may lead to further exacerbation in symptoms and or complications, patient's may require a higher dose than initially prescribed. Otherwise a patient is likely to consume their monthly quota of medicine and suffer for the remaining period. It is inhumane to deny a patient medicinal relief in such circumstances, as it would be to deny increasing a patient's dose of a standard pharmaceutical that would bring symptom relief.

[482] Gotzsche, P.C., Deadly Medicines and Organised Crime. How big pharma has corrupted healthcare. Radcliffe. 2013. ISBN-13 978 1846198847

[483] Downing, N.S., Aminawung, J.A., Shah, N.D., Krumholz,, H.M., Ross, J.S. "Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents 2005-2012" JAMA.(2014); 311(4):368-377.

[484] Ibid.

[485] Ibid; http://naturalsociety.com/drug-labels-contain-70-negative-side-effects-on-average/#ixzz3YBrIzmJi

[486] Barrett, M: Drug Labels Contain 70 Negative Side Effects on Average. Natural Society. 2011. See: http://naturalsociety.com/drug-labels-contain-70-negative-side-effects-on-average; Live Science: Average Drug Label Lists Whopping 70 Side Effects. See: http://www.livescience.com/14293-drug-label-side-effects.html

[487] Young, J., Opinion and Recommended Ruling, Findings of Fact, Conclusion of Law and Decision of Administrative Law Judge in the Matter of Marijuana Rescheduling Petition, Docket No. 86–22, U.S. Department of Justice, Drug Enforcement Administration (1988)

[488] Williamson, E.M, Evans, F.J. Drugs. 2000 Dec;60(6):1303-14.

[489] Ibid; Health Canada: Information for Health Care Professionals. Cannabis (marihuana, marijuana) and the Cannabinoids. Overdose/Toxicity. Para 8.0. p. 94. 2013.

[490] Calabria, B., Degenhardt, L., Hall, W., Lynskey, M. "Does cannabis use increase the risk of death? Systematic review of epidemiological evidence on adverse effects of cannabis use". Drug Alcohol Rev (Review) (2010). 29 (3): 318–30; Ashton ,C.H. "Pharmacology and effects of cannabis: a brief review". Br J Psychiatry (Review) (2001); 178 (2): 101–6.

[491] The personal experience of the author over 13 year period.

[492] Canadians for Safe Access. BC Compassion Club Society and the Victoria Island Compassion Society. Lucas, P., Black, H. and Capler, R. "A Road Map to Compassion . The Implementation of a Working Medicinal Cannabis Program in Canada". 2004.

[493] See: Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 ,2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005 and "Cultivation: Personal Production" in this submission.

[494] Carter, G.T., Weydt, P., Kyashna-Tocha, M., Abrams, D. "Medicinal cannabis: Rational guidelines for dosing." Drugs (2004); 7(5): 464-470.

[495] Marihuana Medical Access Regulations SOR/2001-227 made under the Canadian Controlled Drugs and Substances Act See: Reg 30 & 31

[496] Ibid R. 52.1

[497] The Dignified Access Initiative – Proposal to Implement a Medicinal Cannabis Program for Ontario. 2015. Canadian Medicinal Cannabis Partner and the Medicinal Cannabis Patients Alliance of Canada. See: http://dignifiedaccess.mcpacanada.org

[498] A number of jurisdictions in the USA provide licenses this way.

[499] A number of jurisdictions in the USA set out such criteria. i.e. Delaware USA, Vermont, Maine, and Canada. Similar requirements operate with respect to the cultivation of the opium industry in Victoria.

[500] Regulatory requirement by the cultivators of opium in Victoria

[501] Also useful in event of a product recall and employed in jurisdictions in the USA i.e. Colorado, Illinois, Minnesota.

[502] As used by Steep Hill Halent Laboratories USA.

[503] Regulatory requirement of cultivation of Victorian poppie scheme as well as a regulatory requirement under the Canadian Medicinal Cannabis Scheme.

[504] Regulatory requirement of Canadian Medicinal Cannabis Scheme.

[505] See: Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 ,2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005.

[506] See: Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005.

[507] Ibid.

[508] Ibid.

[509] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005, and Affidavit of Dr. Walsh for the Plaintiffs. See: http://www.johnconroy.com/mmar.htm

[510] Allard –v- R Fed. Crt. B..C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005, and Affidavit of Rocht, J., Health Canada. See: http://www.johnconroy.com/mmar.htm

[511] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005, including Affidavits of King, M and Colasanti, R.See: http://www.johnconroy.com/mmar.htmIbid

Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005,

[513] Ibid.

[514] Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy, Q.C. for the Plaintiffs at p. 2005, and Affidavit of Rocht, J., Health Canada. See: http://www.johnconroy.com/mmar.htm

[515] Allard –v- R Fed. Crt. B.C. Phelan, J. April 30, 2025. Arguments Summation. Transcript. Conroy Q.C. for the Plaintiffs at p. 2005.

[516] Ibid.

[517] Canadians for Safe Access. (2004). Quebec National Institute of Public Health confirms that Health Canada cannabis below 6% THC; CSA proposes a moratorium on research and distribution [press release].

http://safeaccess.ca/pr/csapr17.htm. - See more at: http://www.heretohelp.bc.ca/visions/cannabis-vol5/compassion-clubs#sthash.6MkqUKuU.dpuf

518 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005.

519 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005 and Affidavit of Cain, T. – Health Canada. See: http://www.johnconroy.com/mmar.htm

520 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005 and Affidavit of Rocht, J. – Health Canada. See: http://www.johnconroy.com/mmar.htm

521 Ibid.

522 Ibid.

523 Ibid.

524 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C for the Plaintiffs at p. 2005 and See: Affidavit of Sandvos, C.– Netherlands Dept Health Bureau. See: http://www.johnconroy.com/mmar.htm

525 Mardones, V. "Herbal Cannabis as Medicine: A bio cultural analysis." University of Kent-Canterbury. (Sept 2011).

526 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005.

527 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005.

528 Ibid.

529 any unexpected cannabis yielded over permitted storage quotas could be sold or donated. See: Permitted Quantity to be Supplied and Possessed" in this submission.

530 See The Canadian: Dignified Access Initiative –Harmonised Medicinal Cannabis Program. 2015. Canadian Medicinal Cannabis Partners and Medicinal Cannabis Patients Alliance of Canada. http://dignifiedaccess.mcpacanada.org/docs/hmcp.htm

531 As used by Steep Hill Halent Laboratories USA.

532 Also useful in event of a product recall and employed in jurisdictions in the USA i.e. Colorado, Illinois, Minnesota.

533 Regulatory requirement of cultivation of Victorian opium scheme as well as a regulatory requirement under the Canadian Medicinal Cannabis Scheme.

534 An example of this requirement can be found in the regulatory requirements of the Canadian Medicinal Cannabis Scheme.

535 See: Canadian Association of Medical Cannabis Dispensaries Association Certification Standards for Medicinal Cannabis Dispensaries in Canada. 2013.

536 The state agency might enable temporary registration in the scheme upon lodgment of required documentation, to enable lawful access to cannabis medicine for patient's traveling from interstate and overseas that may be situated in Victoria for some time and who would otherwise be without access to medicine.

537 Current standard of practice under Canadian Association of Medicinal Cannabis Dispensaries Association Certification Standards for Medicinal Cannabis Dispensaries in Canada. (2013) on the basis that prescriptions may be used for up to 12 months.

538 Current standard of practice under Canadian Association of Medicinal Cannabis Dispensaries Association Certification Standards for Medicinal Cannabis Dispensaries in Canada. (2013) on the basis that prescriptions may be used for up to 12 months.

539 Similar to regulations of Medicinal Cannabis Scheme in Mayne, USA.

540 With appropriate amendments to the Drug Poisons and Controlled Substances Act 1981(Vic) to allow for such parties to prescribe under a medicinal cannabis scheme.

541 At times of stress or additional illness, which may lead to further exacerbation in symptoms and or complications, patient's may require a higher dose than initially prescribed. Otherwise a patient is likely to consume their monthly quota of medicine and suffer for the remaining period. It is inhumane to deny a patient medicinal relief in such circumstances, as it would be to deny increasing a patient's dose of a standard pharmaceutical that would bring symptom relief.

542 Allard –v- R Fed. Crt. B.C. Canada. Phelan, J. April 30 2025. Arguments Summation. Transcript. Conroy, J. Q.C. for the Plaintiffs at p. 2005.

543 The Dignified Access Initiative – Proposal to Implement a Medicinal Cannabis Program for Ontario. 2015. Canadian Medicinal Cannabis Partner and the Medicinal Cannabis Patients Alliance of Canada. See: http://dignifiedaccess.mcpacanada.org

544 British Columbia Compassion Club Society, Vancouver, B.C, Canada See: https://thecompassionclub.org

545 Ibid.

[546] Ibid.
[547] Ibid.
[548] Ibid.
[549] Ibid.
[550] Ibid.
[551] Ibid.

ANNEXURE ONE

MEDICINE INFORMATION SHEET

Cannabis

Pronunciation: kan-uh-bis

This medicine is USED FOR:

Although cannabis is used for a wide variety of ailments, rigorous clinical research is still relatively limited due to federal government regulations. Around the globe, however, controlled trials are taking place and more scientific information on the therapeutic effects of cannabis is being established.

Some of the more accepted medical uses of cannabis are for the following ailments:

Alzheimer's Disease: reduce agitation and nighttime tossing and turning, stimulate weight gain.

Amyotrophic Lateral Sclerosis: slow disease progression; reduce pain, appetite loss, depression, drooling.

Chronic Pain: reduce nerve-related (neuropathic) pain, allow opioid treatment at lower doses.

Diabetes Mellitus: slow disease progression, protect from eye disease, reduce neuropathic (nerve) pain, reduce symptoms of heart-muscle disease (cardiomyopathy).

Dystonia: reduce muscle tension and involuntary, painful muscle contractions.

Fibromyalgia: reduce pain and muscle stiffness, improve sleep quality.

Gastrointestinal Disorders: reduce cramping, abdominal pain, acid reflux, intestinal secretion, disease activity.

Glaucoma: reduce intraocular (eye) pressure. **Gliomas/Cancer:** inhibit tumor growth, reduce nausea and vomiting from cancer chemotherapy.

HIV/AIDS: reduce neuropathic pain, anxiety, nausea, appetite and weight loss.

Incontinence: improve bladder control, reduce bladder inflammation/overactivity.

Multiple Sclerosis: reduce pain, spasticity, depression, fatigue, incontinence.

Parkinson's Disease: alleviate L-dopa induced dyskinesias (LID), reduce tremor, rigidity and psychosis symptoms.

Pruritus: reduce itching in conditions such as kidney and liver diseases.

Rheumatoid Arthritis: reduce joint pain and swelling, suppress joint destruction and disease worsening.

Insomnia: induce sleep and/or improve sleep quality.

Tourette's Syndrome: improvement of tics and obsessive-compulsive behavior.

What the active compounds might be:

Cannabichromene (CBC), Cannabidiol (CBD), Cannabidiolic acid (CBDA), Cannabidivarin (CBDV), Cannabigerol (CBG), Cannabinol (CBN), Tetrahydrocannabinol (THC), Tetrahydrocannabinolic acid (THCA), Tetrahydrocannabivarin (THCV), Terpenoids.

What the other compounds might be:

There may be more than 60 other cannabinoids and more than 200 terpenoids in cannabis.

How this medicine is supplied:

Cannabis comes in various forms: dried plant material ("buds", tea leaves), concentrate (hash, "wax", tincture, oil, capsules), topical salve, edible (including drinks).

Do NOT USE this medicine if:

- You are allergic to any cannabinoid or terpenoid.
- You have a history of serious mental disorder such as schizophrenia or severe depression.
- You are pregnant or planning to get pregnant. In addition to the risk of smoking, the use of cannabis when you are pregnant may be a risk factor for sudden infant death syndrome. Uterine exposure to cannabis may also cause behavioral (attention) problems in the child.
- You are nursing.
- Important: there may be other conditions where this product should not be used but which are unknown due to limited scientific information.

BEFORE USING this medicine:

ALWAYS TALK TO YOUR PHYSICIAN, PARTICULARLY IF:

- You have heart disease.
- You have asthma, chronic obstructive pulmonary disease or other disease of the airways.
- You have a history of alcohol abuse or dependence.
- You have a history of drug abuse or dependence.
- You have a history of a serious mental disorder.

HOW TO USE this medicine:

Use this medicine as directed by your doctor. Dosage and frequency of administration will vary according to route of administration (smoke, vaporization, ingestion, skin), percentage of therapeutic ingredients, and other medicines taken. Ask your doctor or collective consultant to explain what dosage, route and frequency is best for you. Remember that concentrates have higher dosages per weight of medicine than other forms. Make sure you give the medicine sufficient time to take effect. This is especially important with the edible form of cannabis where therapeutic effect may take up to 1-2 hours before taking effect. Eating too much medicine too fast may easily occur causing unwanted side effects. Use this medicine only for the length of time recommended by your doctor. It is not recommended to use this medicine in combination with tobacco.

Important SAFETY INFORMATION about this medicine:

- If you have not consumed cannabis before, it would be prudent to have someone with you the first time you use it. It is important to start by using small quantities. Stop if you begin to feel confused or agitated.
- After you stop using cannabis, it remains in your system for several weeks to months. Therefore, during this time, tests that screen for cannabis may be positive.
- Cannabis may interact with several drugs. Tell your doctor which prescription drugs, nonprescription drugs and herbal products you are currently taking, particularly:
  - Any drugs that slow down the central nervous system, causing drowsiness. This may include sleeping pills, tranquilizers, some pain medications, some antihistamines or cold medications or seizure medications.
  - Antiviral drugs used in the treatment of HIV/AIDS.
- CANNABIS MAY IMPAIR YOUR ABILITY TO DRIVE OR OPERATE HEAVY MACHINERY. This can last up to 24 hours after consuming.

Possible SIDE EFFECTS of this medicine:

- From Initial use:
  - When you first start consuming cannabis, you may experience mood reactions such as euphoria, relaxation, time-distortion, perception of enhanced sensory experiences, loss of inhibitions, anxiety, paranoia, agitation, amnesia, delusions or hallucinations.
  - Fast heartbeat; this may be more of a problem if you have heart disease.
  - Facial flushing or red eyes, dry mouth, headache.
  - Right after consuming cannabis you may get dizzy or feel faint when you get up from a lying or sitting position. Try getting up more slowly. If lying down, sit on the edge of the bed and let your feet dangle for 1 to 2 minutes, then stand up slowly.
- From Long-term use:
  - Wheezing or a chronic cough, if the medicine is smoked.
  - May impair short-term memory attention and concentration. These effects usually disappear after you stop using cannabis.

If OVERDOSE is suspected:

It is possible that the above mentioned side effects occur. Usually these will resolve themselves within a short period of time when medication is stopped. Often fresh air, staying hydrated and eating will help. Contact your doctor immediately if symptoms persist.

Proper STORAGE of this medicine:

Store in a tightly closed container in a cool, safe and secure place. Store away from heat, moisture and light.

GENERAL INFORMATION:

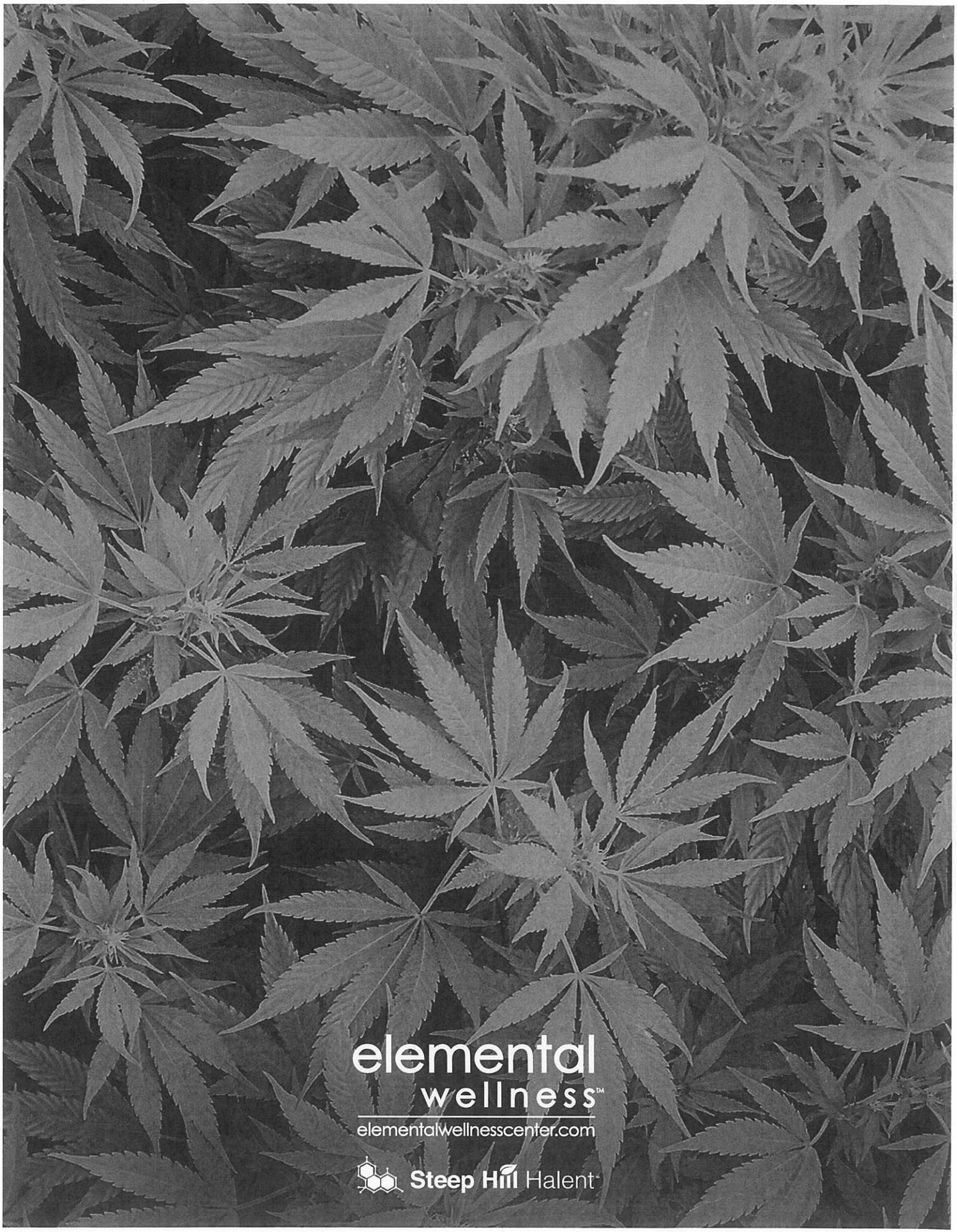
- If you have any questions about this medicine, please talk with your doctor, collective consultant or other health care provider.
- This medicine is to be used only by the patient for whom it is recommended. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.
- Check with your collective consultant about how to dispose of unused medicine.
- This information is a summary only. It does not contain all information about this medicine.

KEEP THIS MEDICINE OUT OF REACH OF CHILDREN AND PETS.

elemental wellness™

 Issue Date: 7-29-2013

ANNEXURE TWO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Steep Hill Halent

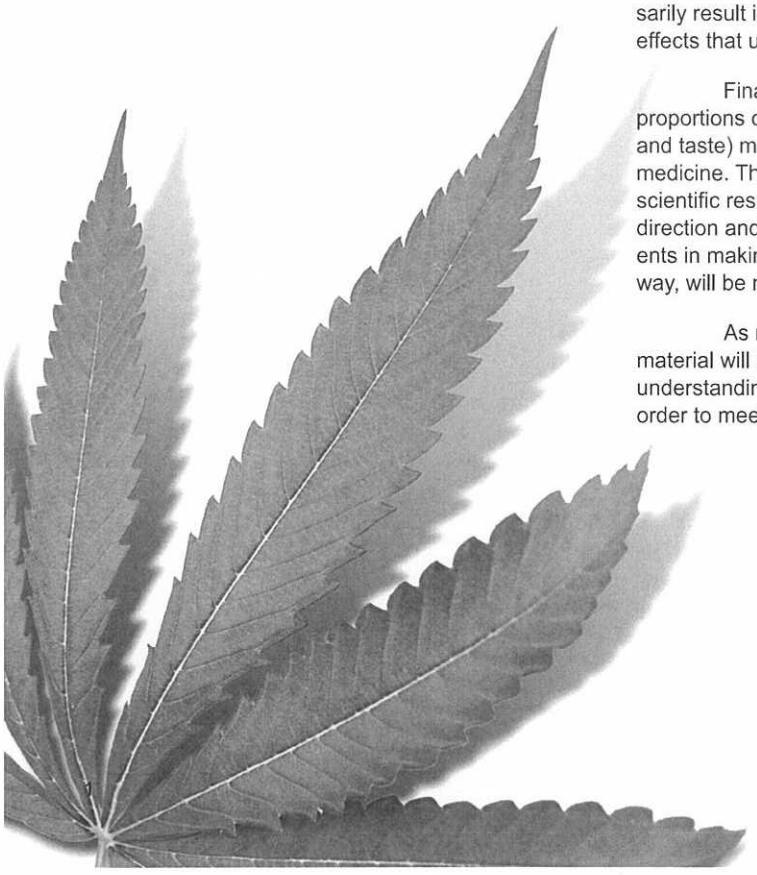
INTRODUCTION

In continuing its efforts to provide the best holistic wellness care to its members, **Elemental Wellness** is pleased to provide this educational material to its members, staff and community physicians. The purpose of this information is to educate us on the latest scientific concepts and understanding of medical cannabis so that we may better benefit from its diverse medicinal properties. Understanding this "pharmaceutical treasure trove" will hopefully make its utilization more efficient and effective (and less daunting for those who are new to this ancient herbal medicine).

Helping us to better understand medical cannabis are the advances in laboratory analysis (now available to collectives) combined with the ongoing research taking place around the world. Much of this research is aimed at delineating the therapeutic effects of the various chemical compounds in cannabis, especially the cannabinoids and terpenoids. Two recent articles illustrating this development are those by Izzo, et al. (2009) and Russo (2011). An excellent video by Lindsey Ward on medical cannabis and its impact on human health can be found online at: http://www.youtube.com/watch?v=8Md2WNqqxTQ.

Another key to better understanding of medical cannabis is awareness that the chemical compounds available in the plant change with how the plant is processed and administered. Potential therapeutic benefits will vary if the cannabis is processed/administered in raw (unheated), heated or aged (degraded) form.

Also knowing that the various compounds in cannabis may modulate each other in synergistic or antagonistic ways is important. For example, the cannabinoid CBD will lessen to some degree the psychotropic effects of the cannabinoid THC, while the terpenoid α-pinene will synergize the bronchodilator effects of THC. This complexity of interaction means that medical cannabis should be seen in the light of an herbal medicine, where to extract a so-called "active ingredient" will not necessarily result in the full range of therapeutic effects, or may produce unwanted side effects that usually do not occur when the whole herb is administered.



Finally, knowing that each strain of cannabis has potentially vastly different proportions of cannabinoids and terpenoids (often expressed in terms of color, smell and taste) means that one needs to be strain specific when discussing cannabis as medicine. This is a difficult step, but one that modern laboratory analysis and scientific research is now making possible. **Elemental Wellness** is working in this direction and hopes that this educational material will assist caregivers and recipients in making a choice as to which strain, in what form, and administered in which way, will be most beneficial to them.

As new research in medical cannabis becomes available, this educational material will be revised to reflect the latest insights. In this way we hope that our understanding and use of medical cannabis will continue to grow in effectiveness in order to meet the needs and maximize the wellness of our members.

CANNABINOIDS

CBGA	Cannabigerolic Acid
CBGVA	Cannabigerivarinic Acid
✓ CBG	Cannabigerol
CBGV	Cannabigerivarin
THCA	Tetrahydrocannabinolic Acid
THCVA	Tetrahydrocannabivarinic Acid
THC (Δ9)	Δ9-tetrahydrocannabinol
THCV	Tetrahydrocannabivarin
CBNA	Cannabinolic Acid
THC (Δ8)	Δ8-tetrahydrocannabinol
✓ CBN	Cannabinol
CBDA	Cannabidiolic Acid
CBDVA	Cannabidivaric Acid
✓ CBD	Cannabidiol
CBDV	Cannabidivarin
CBCA	Cannabichromic Acid
CBCVA	Cannabichromivaric Acid
CBC	Cannabichromene
CBCV	Cannabichromivarin
CBLA	Cannabicyclol Acid
CBL	Cannabicyclol

TERPENOIDS

Smells and Therapeutic Effects

α-PINENE

Pine needles

Anti-bacterial
Anti-fungal
Anti-inflammatory
Bronchodilator

β-CARYOPHYLLENE

Black Pepper

Clove

Anti-bacterial
Anti-cancer
Anti-fungal
Anti-inflammatory
Anti-septic

BORNEOL

Camphor

Analgesic
Anti-insomnia
Anti-septic
Bronchodilator

CARYOPHYLLENE OXIDE

Eucalyptus

Anti-fungal
Anti-ischemic

CINEOL

Tea Tree

Anti-bacterial
Anti-depressant
Anti-inflammatory
Anti-ischemic
Bronchodilator

CITRONELLOL

Rose

Anti-cancer
Anti-inflammatory
Anti-insomnia
Anti-spasmotic

HUMULENE

Hops

Anorectic
Anti-cancer
Anti-bacterial
Anti-inflammatory

LIMONENE

Citrus

Anti-anxiety
Anti-bacterial
Anti-cancer
Anti-depressant
Anti-fungal
Bronchodilator

LINALOOL

Lavender

Anti-anxiety
Anti-bacterial
Anti-convulsive
Anti-depressant
Anti-insomnia

MYRCENE

Lemongrass

Mango

Analgesic
Anti-cancer
Anti-inflammatory
Anti-insomnia
Anti-spasmotic

NEROLIDOL

Wood

Citrus rind

Anti-fungal
Anti-insomnia

PHYTOL

Green Tea

Anti-insomnia

TERPINOLENE

Lilac

Apple

Anti-bacterial
Anti-fungal
Anti-insomnia
Anti-septic

NOTES ON CHARTS 1, 2 and 3

The following charts reflect most of what is presently known on the potentially therapeutic chemical compounds in cannabis, how they are formed, and how they relate to each other. Only 21 cannabinoids and 13 terpenoids are listed. There is still much to be learned.

The charts should be read horizontally and vertically:

Horizontally: which cannabinoids can be found in which physical state of cannabis (raw, heated, aged). Raw refers to the fresh plant. Aged refers to the effects of UV-light, oxidation, and isomerization; in other words: degradation.

Vertically: how do the cannabinoids relate to each other; where do they come from?

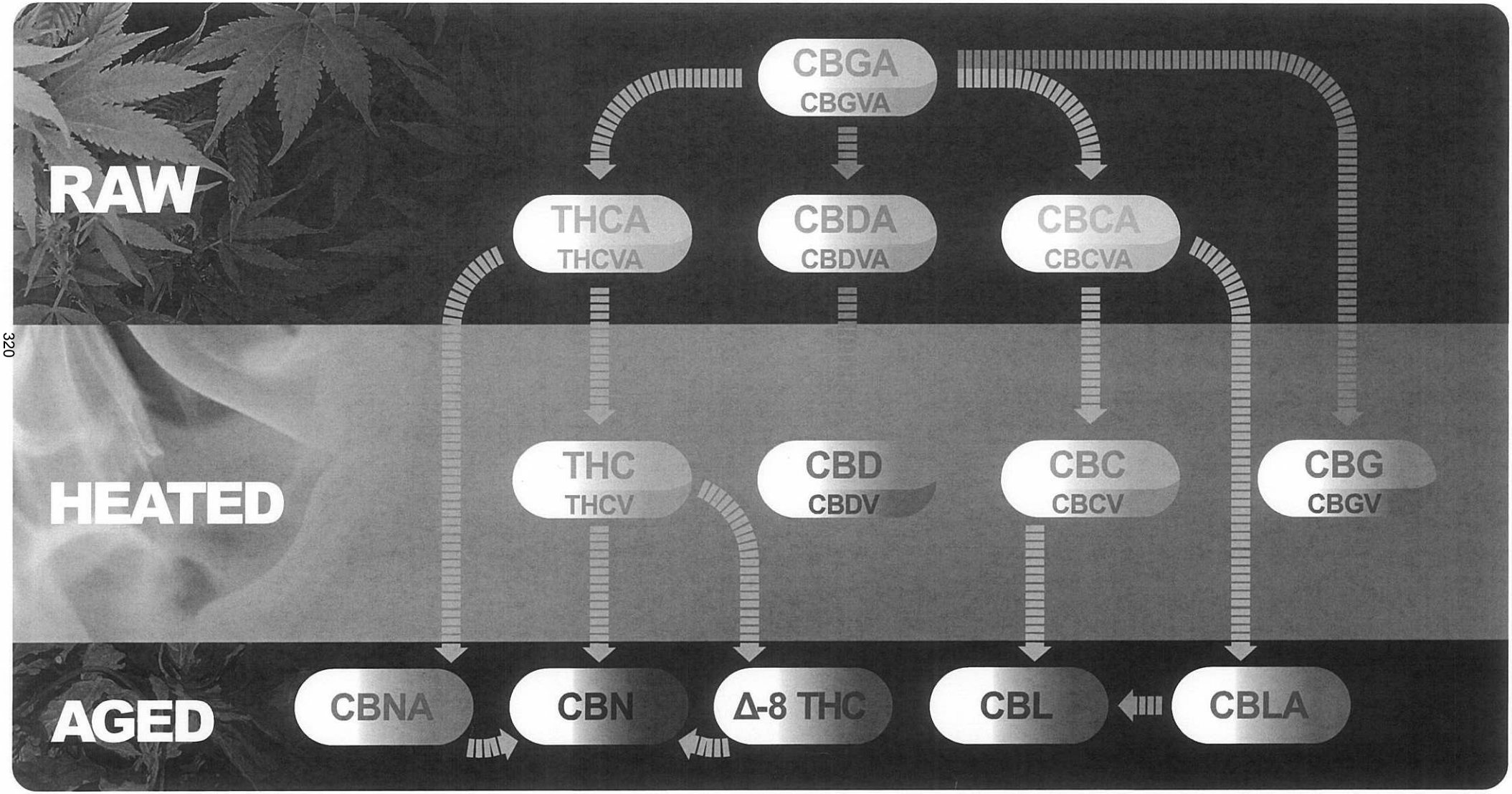
In general, the amount of divarinic cannabinoid (those with "V" in the acronym) is always less than the olivetolic cannabinoid. In the charts, this is reflected in the smaller font size of the acronym.

The charts do not imply that all cannabinoids listed are always detectable in the various strains currently available. Breeding has mainly focused on increasing the amount of THC. Recently CBD is getting a lot of attention, and strains high in CBD are now being bred. Hopefully other strains with significant amounts of other cannabinoids will be available soon.

Since terpenoids are more volatile than cannabinoids, their presence is more closely related to freshness and temperature. The fresher and cooler the cannabis (upper part of the chart), the more the terpenoids peculiar to the strain are preserved. Therefore, as one goes down the chart, terpenoids listed in the different physical states of cannabis may or may not be available in amounts of therapeutic significance.

UNDERSTANDING MEDICAL CANNABIS

Cannabinoids and Their Relationships



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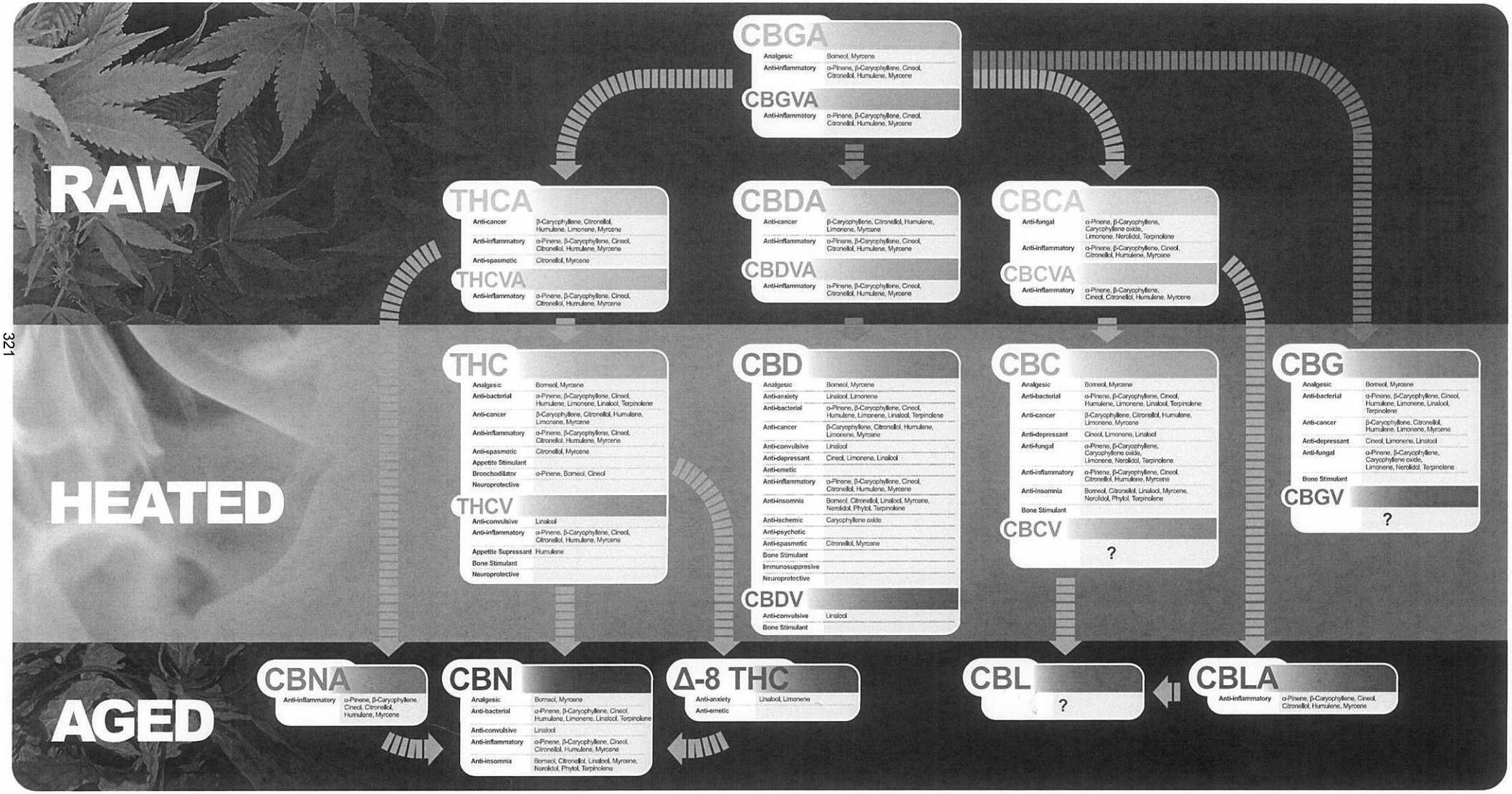
UNDERSTANDING MEDICAL CANNABIS

Cannabinoids, Therapeutic Effects and Synergistic Terpenoids



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THCA

Anti-cancer	β-Caryophyllene, Citronellol, Humulene, Limonene, Myrcene
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene
Anti-spasmotic	Citronellol, Myrcene

THCVA

Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

THC

Analgesic	Borneol, Myrcene
Anti-bacterial	α-Pinene, β-Caryophyllene, Cineol, Humulene, Limonene, Linalool, Terpinolene
Anti-cancer	β-Caryophyllene, Citronellol, Humulene, Limonene, Myrcene
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene
Anti-spasmotic	Citronellol, Myrcene
Appetite Stimulant	
Bronchodilator	α-Pinene, Borneol, Cineol
Neuroprotective	

THCV

Anti-convulsive	Linalool
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene
Appetite Supressant	Humulene
Bone Stimulant	
Neuroprotective	

CBNA

Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

Δ-8 THC

Anti-anxiety	Linalool, Limonene
Anti-emetic	

CBN

Analgesic	Borneol, Myrcene
Anti-bacterial	α-Pinene, β-Caryophyllene, Cineol, Humulene, Limonene, Linalool, Terpinolene
Anti-convulsive	Linalool
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene
Anti-insomnia	Borneol, Citronellol, Linalool, Myrcene, Nerolidol, Phytol, Terpinolene

CBDA

Anti-cancer	β-Caryophyllene, Citronellol, Humulene, Limonene, Myrcene
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

CBDVA

Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

CBD

Analgesic	Bomeol, Myrcene
Anti-anxiety	Linalool, Limonene
Anti-bacterial	α-Pinene, β-Caryophyllene, Cineol, Humulene, Limonene, Linalool, Terpinolene
Anti-cancer	β-Caryophyllene, Citronellol, Humulene, Limonene, Myrcene
Anti-convulsive	Linalool
Anti-depressant	Cineol, Limonene, Linalool
Anti-emetic	
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene
Anti-insomnia	Bomeol, Citronellol, Linalool, Myrcene, Nerolidol, Phytol, Terpinolene
Anti-ischemic	Caryophyllene oxide
Anti-psychotic	
Anti-spasmotic	Citronellol, Myrcene
Bone Stimulant	
Immunosuppresive	
Neuroprotective	

CBDV

Anti-convulsive	Linalool
Bone Stimulant	

CBCA

Anti-fungal	α-Pinene, β-Caryophyllene, Caryophyllene oxide, Limonene, Nerolidol, Terpinolene
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

CBCVA

Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

CBC

Analgesic	Borneol, Myrcene
Anti-bacterial	α-Pinene, β-Caryophyllene, Cineol, Humulene, Limonene, Linalool, Terpinolene
Anti-cancer	β-Caryophyllene, Citronellol, Humulene, Limonene, Myrcene
Anti-depressant	Cineol, Limonene, Linalool
Anti-fungal	α-Pinene, β-Caryophyllene, Caryophyllene oxide, Limonene, Nerolidol, Terpinolene
Anti-inflammatory	α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene
Anti-insomnia	Borneol, Citronellol, Linalool, Myrcene, Nerolidol, Phytol, Terpinolene
Bone Stimulant	

CBCV

?

CBLA

Anti-inflammatory α-Pinene, β-Caryophyllene, Cineol, Citronellol, Humulene, Myrcene

CBL

?

ANNEXURE THREE

Guidelines for the Community-Based Distribution of Medical Cannabis in Canada

May 2006

Rielle Capler
British Columbia Compassion Club Society

Philippe Lucas
Vancouver Island Compassion Society

Guidelines for the Community-Based Distribution of Medical Cannabis in Canada

Table of Contents

I. BACKGROUND

1. Cannabis

Cannabis is a natural herb with a long history of medical use. It has been shown to alleviate suffering from a large number of medical conditions and symptoms and is used as either a complement or an alternative to pharmaceutical, over-the-counter, or "street" drugs. Research and experience have indicated that cannabis can be safely self-administered and self-titrated.

Currently the recreational use of cannabis remains illegal in Canada. Medical use is only legal under severely restricted circumstances through Health Canada's Medical Marijuana Access Division. Established in 1999, this program has licensed just over 1000 people in Canada to use cannabis legally, and the official legal supply of cannabis remains problematic. [1]

2. Community-Based Medical Cannabis Dispensaries

Medical cannabis dispensaries, also called compassion clubs, supply cannabis for therapeutic use upon a valid recommendation or confirmation of diagnosis from a licensed health care practitioner.

Compassion clubs reflect a community-based response to the suffering of critically and chronically ill Canadians who might benefit from the medical use of cannabis. They provide access to diverse strains of high quality raw plant cannabis and cannabis-based products in a secure environment conducive to healing. They also provide education about the safe and effective use of these products. In addition, some dispensaries subsidize access to other natural health care services that would otherwise be unavailable to their clients.

Compassion clubs also advocate for clients in regards to the use of cannabis as a medicine in an illegal and highly stigmatized context. This has included giving input and feedback to Health Canada's medical marijuana program, and testifying before the Special Senate Committee on Illegal Drugs and the House of Commons Special Committee on the Non-Medical Use of Drugs. Several compassion clubs work with local, provincial and national health care organizations, initiate and participate in research studies, and give presentations to the community at large, colleges and universities, and at international, national and local conferences. [2]

Pre-dating the federal medical cannabis program, the history of Canada's compassion clubs dates back to 1997, when the British Columbia Compassion Club Society opened its doors in Vancouver as a non-profit medical cannabis distribution organization. Since that time, a number of similar dispensaries have been established throughout Canada, but because of the overwhelming legal obstacles facing these organizations, only a few have been able to remain in operation for an extended period of time. Together, compassion clubs currently serve about 10,000 people living in Canada who use cannabis medicinally.

Communities, law enforcement, and criminal courts across Canada have shown support and tolerance for compassion clubs that self-regulate to ensure their services are strictly for medical purposes.[3] The Senate Special Committee on

1. It is often cited that there are approximately 400,000 Canadians currently using cannabis for therapeutic purposes. This estimate is based on one study conducted in Ontario that found that 1.9% of the population aged 18 years and over reported that they use marijuana for medical purposes (Ogborne AC, Smart RG, Adlaf EM. Self-reported medical use of marijuana: a survey of the general population. Canadian Medical Association Journal, June 13, 2000;162(12):1685-1686.) This is most likely an underestimate. In British Columbia alone, it is estimated that about 7%, or 290,000 people, use cannabis for therapeutic purposes (Vancouver Sun. March 22nd, 2004. "Medical Marijuana Coming to B.C. Pharmacies". Quote from Robin O'Brien, Director of Vancouver's Pharmacotherapy Consulting Group.)

2. The VICS and BCCCS participated in a consultation with key stakeholders in Health Canada's medical marijuana program in February of 2004. For this occasion they produced a document titled "Roadmap to Compassion," which identifies many of the roadblocks Canadians have been experiencing with the MMAR program, and proposes solutions to overcoming them. Additionally, the Senate Special Report on Illegal Drugs report recommends that Health Canada license and work with Compassion Clubs. Links to this document and to the Senate Report can be found in Section VII. 1.

3. The BC Compassion Club Society's *Operational Standards for the Distribution of Medical Cannabis* (written by Hilary Black and Rielle Capler, 2003) outlines the practices of this organization. It has been used as a reference by other compassion clubs, both nationally and internationally, and has served as the foundation for this document. See Section VII. 1.

Illegal Drugs and other government bodies have recommended that these organizations be licensed and legally recognized. However, despite the well-established and constitutionally protected right for Canada's sick and suffering to access cannabis, and the crucial and acknowledged role of compassion clubs in providing cannabis to those in need, Canadian dispensaries are currently operating without legal sanction or protection.

3. Harm Reduction

Based on a philosophy of harm reduction and improved public health, compassion clubs effectively balance legal concerns around the criminal prohibition of cannabis with a respect for the personal autonomy of individuals in making important healthcare decisions. Currently, this balance entails engaging in civil disobedience while striving to operate in a manner that addresses the concerns of all relevant stakeholders.

By offering a safe and secure means of access to high quality medical cannabis, compassion clubs reduce the potential harms often associated with illicit distribution. Medical cannabis users who are not clients of compassion clubs must obtain cannabis from other sources. These sources may be unreliable, unsafe, and difficult to find, and the cannabis they have available may be of lower quality, less effective, and/or at higher cost than that provided through most community-based dispensaries.

A well-run compassion club also reduces the risk of potential criminal repercussion associated with illicit cannabis distribution. Law enforcement officers and courts may choose to respect and recognize ID cards from recognized dispensaries as adequate proof of legitimate medical use. Courts have given discharges to compassion club operators who run their clubs in a transparent, accountable and responsible manner.

4. Purpose of Guidelines

It is imperative to protect the rights of Canadians to access medical cannabis strains and products that best suit their particular condition, are cultivated and produced in a method of their choice, and accessed through the source or outlet that best serves their needs.

The following guidelines carefully balance client autonomy, the diversity of individual dispensaries, local community concerns, and adherence to municipal, provincial and federal laws, all within the context of Canada's current cannabis policy.

These guidelines are designed to:

1. Provide a base-standard for self-regulation of dispensaries based on current best practices in Canadian compassion clubs;

2. Support medical cannabis dispensaries in providing a high standard of care that clients can and should expect;

3. Help both distributors and end-users achieve maximum safety and

therapeutic potential within a setting that is conducive to healing;

4. Formalize the good reputation established by compassion clubs, thus ensuring those with medical need have continued access;

5. Promote an understanding of medical cannabis dispensary practices to all levels of government, the justice system, law enforcement, and community partners;

6. Allow for effective cooperation amongst dispensaries utilizing the same base-standards of operation.[4]

7. Organize participating dispensaries into a more cohesive voice for the legitimization and legal acceptance of community-based cannabis production, research and distribution.

These guidelines are not intended to imply that organizations or individuals that are dispensing cannabis in another context or manner are not fulfilling legitimate purposes.

Dispensaries should continue to monitor the political and legal climate, as well as research findings, and adjust these guidelines accordingly.

4. Note that individual dispensaries may exceed these base-standards, and that adherence to these may not infer interchangeable membership or exchange of product between dispensaries

II. ACCESS TO DISPENSARIES

1. Eligibility Requirements

a. Age/Parental Permission

Community-based dispensaries should only distribute cannabis to those 18 years old and over, unless applicants have written consent from a parent or legal guardian.[5] This age-based restriction reflects the legal age of adulthood, while also recognizing that some people under the age of 18 may also need access to a safe source of medical cannabis. In recognition that the legal status and stigma of cannabis use may pose particular difficulties for those under 18 in accessing medical cannabis, dispensaries will continue to monitor the political and legal climate regarding this requirement.

b. Healthcare Practitioner Support

Clients of compassion clubs must have the support of an appropriately licenced healthcare practitioner to verify their medical condition and the therapeutic nature of their cannabis use. Medical cannabis use generally refers to applications that alleviate the suffering of specific symptoms and medical conditions, and to improve the overall sense of well-being. [6]

Despite resistance from their provincial and federal regulatory bodies, an increasing number of physicians support the medical use of cannabis by their patients, and are the main source of patient recommendations for access to medical cannabis.

Given that cannabis is an herbal medicine, recommendations for its use may also be permitted from doctors of Traditional Chinese Medicine and Naturopaths. These health care practitioners are experienced with herbal medicine and have licensing bodies and governing associations necessary for legal recognition and to ensure a certain quality of care and expertise.

c. Recommendations and Confirmation of Diagnosis

Obtaining support from healthcare practitioners for therapeutic cannabis use can be problematic, particularly in rural areas of the country. Many health practitioners refuse to recommend the use of cannabis, even if they believe that it may be therapeutically beneficial to their patients. Although some refusals are due to potential medical concerns, many are the result of the illegal status and social stigma of cannabis, pressure from professional associations and colleges, fear of liability and pressure from insurers, a lack of awareness of the latest clinical research, and general discomfort with the prescription of herbal medicines.

In recognition of this problematic political/legal/regulatory situation, many dispensaries have found it necessary to accept a simple proof of condition for certain ailments rather than requiring an actual recommendation for the use of cannabis. This can help balance both the dispensary's and the local community's need to ensure the legitimacy of the patient's medical claim, while also addressing the patient's need for safe and timely access to medical cannabis.

5. Compassion clubs may chose to require a higher age of entry in recognition of provincial or community norms.

6. It should be noted that while many legitimate medical cannabis users choose to use cannabis after hearing of and/or experiencing its therapeutic benefits, self-referral is not sufficient for access to compassion clubs in the current legal climate.

Therefore, in order to not unduly restrict availability of cannabis to persons who may receive health benefits from its use, a confirmation of diagnosis from an approved health care practitioner is the base requirement for access to a compassion club for those suffering from the following conditions:

HIV/AIDS, ADHD, Arthritis, Brain/Head Injury, Cancer, Colitis, Chemotherapy, Crohn's Disease, Epilepsy, Fibromyalgia, Glaucoma, Hepatitis C, Irritable Bowel Syndrome, Migraines, Multiple Sclerosis, Muscular Dystrophy, Nausea (chronic and debilitating), Pain (chronic), Paraplegia/Quadriplegia, Parkinson's Disease, Radiation Therapy, Seizure disorders, Sleep Disorders, Substance Addiction and Withdrawal.

The above list of conditions is not comprehensive and should be reviewed and modified periodically in light of emerging research or changing social/legal conditions. Any other condition requires an actual recommendation for the use of cannabis from a healthcare practitioner.

It should be noted that some health care practitioners refuse to even confirm their patient's diagnosis, highlighting the necessity for legal reform and professional education. In the meantime, dispensaries must facilitate this process a much as possible to assist their clients in getting the care that they require.

d. Documentation

Ideally, each compassion club will have a form for health care practitioners to fill out. The form will provide health care practitioners the opportunity to both confirm the diagnosis and recommend the use of cannabis. It will also allow them to indicate if they do not recommend the use of cannabis and to state their reasons.

Since experience suggests that some health care practitioners will not feel comfortable filling out these forms, the conditions that require a diagnosis only (see above section c) may be written on prescription pads or practitioner letterhead. In some cases, other government forms that indicate a medical diagnosis supported by a practitioner signature (i.e. disability forms) may be acceptable to confirm an applicant's condition. Prospective clients can also sign release of information forms, requesting that their practitioner release relevant medical information to the compassion club for the confirmation of a health condition.

To ensure the legitimacy of medical documentation, all forms must be faxed to the dispensary directly from the health care practitioner's office, and the dispensary must confirm the origin of the fax. Additionally, the legitimacy of health care practitioners must be verified with their respective licensing bodies.

e. Special Consideration: Mental Health Conditions

Mental health conditions may be the primary or secondary medical reason for the use of cannabis. Some compassion club clients have recommendations for the use of cannabis for mental health conditions such as bi-polar, schizophrenia,

and PTSD. Many clients suffering from critical or chronic physical conditions also experience mental health problems such as depression and anxiety.

Research suggests that cannabis can be extremely effective in alleviating the symptoms of many mental health conditions. However, in some cases, cannabis use may not be beneficial and may prove deleterious to mental health. Therefore, it may be of benefit for the clients' healthcare provider to be aware of their use of cannabis through the compassion club, so that all parties can work together to effectively monitor and treat the client's condition.

As such, it is recommended that compassion clubs strive to get a recommendation for the use of cannabis in addition to a confirmation of diagnosis for mental health conditions. Clubs should also have a system in place to carefully assess and monitor clients with severe mental health conditions to ensure cannabis is of continued benefit to them. Tailored advice on strain selection and drug interactions should also be given to clients with mental health conditions.

Dispensaries should track current research in this area, and adjust assessment and treatment protocols accordingly.

2. Registration Requirements

a. Personal Information

Upon registering with a compassion club, specific personal information must be collected from the client in order to maintain the highest quality of service possible.

i. Personal information and emergency contact info.
ii. Detailed information regarding conditions, symptoms, and use of other medications.
iii. Previous use of and experience with cannabis.
iv. Other relevant info: pregnancy, eating and sleeping habits, allergies, use of other drugs including tobacco, alcohol, cocaine, heroin and methadone.
v. Photo ID

b. Consent Form

Clients must sign a witnessed consent form designating the Club as their agent to procure cannabis on their behalf, and agreeing that this cannabis is for their personal use only and that they are aware that redistribution will result in expulsion.

c. Rights and Responsibilities

Documents or contracts detailing the clients' rights and responsibilities within the organization promote a safe, friendly and secure environment for all clients and staff, encourage respect for the neighbourhood and local community,

and ensure consistent daily operations around the distribution of cannabis. Dispensaries should develop clear repercussions for infractions of these rights and responsibilities, and a process for their implementation and enforcement. There should be no tolerance for redistribution, and any evidence of re-sale of medications procured from a compassion club should be grounds for an immediate loss of membership privileges.

(See Section VII. 2 for links to forms)

III. CLIENT EDUCATION

Compassion clubs encourage their clients to make informed and educated choices in regards to their healthcare. It is important that people using cannabis as a medicine are equipped with all of the information necessary to medicate safely and effectively.

Upon registering at a compassion club, clients should be given a thorough orientation session that is tailored to their personal healthcare needs. It is recommended that this session include the following areas of information:

1. Introduction to the Plant

Providing medical cannabis users with information about the cannabis plant and cannabinoids will promote an understanding of this medicine, allowing them to use it more effectively.

2. Strain Selection and Effects

Strains of cannabis from the Indica or Sativa genus have very different effects (as do many sub-species). These differences must be explained in order for a client to relieve their symptoms effectively and to be aware of potential side effects, both desirable and undesirable, associated with different strains. It must also be acknowledged that these are general tendencies and that effects vary from person to person. Clients may be given "tracking sheets" to keep track of the strains they have used and their effects.

3. Dosage

Since there is no threat of lethal toxicity from cannabis use, self-titration is the most efficient and effective method of dosage selection. Dispensaries should counsel clients on how to achieve the proper dosages for different modes of administration. Emphasis should be on using the smallest amount possible to achieve the desired effect. This allows the client to reduce costs, as well as achieve maximum therapeutic potential with the lowest amount of potential side effects.

4. Potency

Potency is an important factor in the overall efficacy of cannabis. Choosing a strain with the desired potency allows a client to ingest the smallest amount possible to achieve a desired effect.

5. Tolerance

With some cannabis users, tolerance to cannabis may develop through prolonged use of the same strain. Using a variety of strains will minimize therapeutic tolerance. Taking a treatment "holiday" from cannabis use altogether will also reduce tolerance.

6. Dependence and Withdrawal

When using any substance it is important to be aware of potential for dependence and withdrawal. There is no physical dependence from either chronic or periodic administration of cannabis. There are no significant withdrawal effects when cannabis use is ceased or decreased, however some people may experience sleeplessness, irritability, and loss of appetite. These symptoms are usually mild and short-lived (i.e. 3 days). There may be signs of some psychological dependence since symptom relief will also be decreased when use is ceased. Clubs should provide information to clients about these important considerations.

7. Ingestion Options

Reviewing the various forms of ingestion (i.e. smokeables, edible products, tinctures and teas) and how they differ from each other in terms of potency, time of onset, duration, and overall effect will assist clients in selecting the most effective treatment for their particular symptoms or condition, and help them to use whole-plant cannabis and bi-products safely and effectively.

8. Safe Smoking Techniques

Smoking cannabis may lead to respiratory irritation, especially with prolonged and heavy use, which is sometimes the case for those with chronic illnesses. There are several techniques and tools that can be used to reduce irritation (e.g. not holding the smoke in, and use of various smoking implements such as pipes and vaporizers). These should be reviewed with clients

9. Side Effects and Safe Use

There are some potential effects of cannabis that are not therapeutic (e.g. dizziness, increased heart rate, anxiety, dry mouth). These can be mitigated through education and awareness. As well there are some practical concerns (e.g. driving while if impaired, mixing with alcohol, sharing joints) that should be reviewed to ensure safe use. All clients should be able to make educated and informed decisions in regards to their medical use of cannabis.

10. Quality

Clients should be informed of the quality standards of each dispensary and how these are achieved (i.e. lab testing, production facility inspections). Clients should also be made aware of how to judge quality of products for themselves in terms of tactile and visual inspections.

11. Contraindications and Drug Interactions

Cannabis has been used for thousands of years without record of a single related death. However some research suggests that there may be some medical conditions that could potentially pose concerns in regards to the therapeutic application of cannabis. Additionally, many medical cannabis users may also be using pharmaceutical drugs for their medical condition. While some research indicates that there is the possibility that cannabis may increase or decrease the effectiveness of other medications, current research from pharmaceutical companies suggests that there are no significant drug interactions in regards to cannabis. On the whole, most cannabis users report no significant interactions, although many find that they can reduce their dosage of some their prescription medications with cannabis use, particularly opiate-based painkillers.

Additionally, cannabis can mitigate many negative side effects of prescription medications or treatments, which in some cases may be the primary reason for its therapeutic use. Operators of dispensaries have an ethical responsibility to educate themselves and their clients in regards to potential drug interactions or contraindications to cannabis use, and to stay up to date with emerging clinical cannabis research.

12. Political Climate and Legal Risks

It is important to inform club clients of the current state of the laws, which may be unclear from media and police sources and may be in a state of flux. It is still illegal in Canada to possess, grow, or distribute cannabis. Clients must be aware of the risks of criminal persecution in their particular region, and must know their rights in order to avoid the harmful effects of arrest, cannabis seizure, imprisonment and criminal record. Client should also be made aware of Health Canada's medical marijuana program, which is currently the only legally sanctioned avenue for access. While clubs do not require clients to have a Health Canada license, clients should be able to make an informed choice about participating in the programme.

(See Section VII. 3 for links to more information about the above topics)

IV. DISPENSING CANNABIS

1. Valid ID

Dispensaries will only distribute to clients who present valid ID that identifies them as clients of the dispensary.

2. Quantity Restrictions

Due to clients' budget restrictions, health considerations, and personal convenience, dispensaries must make available to clients the option to purchase smaller or larger quantities at one time. To address concerns of diversion, dispensaries must reserve the right to limit individual client purchases. Dispensaries reserve the right to retain enough cannabis on site to fulfill all potential patient needs.

3. Variety of Strains

In order to effectively treat a wide variety of symptoms and conditions, offering a variety of strains is essential.

4. Cannabis Products

To address diverse client needs, it is important to have a variety of cannabis products available. These products may include:

- Edible Products. Ideally some should be wheat, dairy and sugar-free, as many clients may have to avoid these ingredients in their diets.
- Cannabis-infused cooking oil and butter. These can be used for cooking or for direct oral ingestion.
- Hashish. This form of cannabis provides a concentrated dose of cannabinoids, allowing a patient to consume less plant matter to achieve the desired therapeutic effect.
- Tinctures. Typically alcohol-based and available in drops and/or spray form, and designed to be absorbed through the mucous membranes in the mouth. Glycerin-based tinctures can be effective for clients who do not use alcohol.

5. Selection Support

Clients should be made aware of all relevant information about the strains, such as the effects and organic cultivation status. Dispensary staff should be well informed about the strains and products being distributed. Gathering feedback from clients on the efficacy of each strain can provide valuable data to equip staff in assisting clients to select the right strain. Cannabis should be displayed in a well-lit and clean display area so that clients can properly view and select their medications.

6. Handling and Storage

Clean hands, gloves or tongs must be used while handling the cannabis.

Cannabis should be stored in a cool, dark and dry location. It is essential that cannabis be stored in food-safe containers to avoid any contamination during storage or transportation.

7. Packaging

ideally, cannabis distributed by compassion clubs should be labeled. The label should contain the name of the strain, batch, quantity, as well as clearly indicate that it is for medical use and not intended for resale.

8. Pricing

Medical cannabis must be affordable to those in need. It is imperative that this medicine be covered by provincial and private healthcare insurance plans, as are pharmaceutical medicines used to treat the same conditions. In the meantime, Clubs must strive to offer clients the lowest price possible, and attempt to provide donations when available.

9. Sales Records

Individual client purchases must be accurately recorded with the goal of improving individual treatment, as well as to ensure that quantities being purchased do not suggest re-distribution. Clients may have access to this information at any time.

10. Purchasing Options

Due to the severity of illnesses or the location of residence of some clients, there should be alternatives to purchasing their medicine in person at the dispensary. Some options include assigning a designated purchaser or caregiver, providing a delivery service, and/or establishing a "mail-out" program. Since due diligence must be taken to ensure the medicine goes directly to the client, each dispensary should create clear procedures for such programmes.

11. Right to Refuse Service

Dispensaries must have the right to refuse service should a client not produce valid I.D., interfere with the safe, friendly and secure environment for all clients and staff and with the smooth daily operations around the distribution of cannabis, or if they become rude, violent or disrespectful of the staff, fellow clients, or members of the community at large.

12. Visitors

To support dispensary clients who are traveling away from their home community, dispensaries can, at their discretion, offer medicine to clients of other clubs that adhere to the basic eligibility guidelines (see above Section II).

To ensure proper documentation, all visitors must provide the following to the host dispensary:

- Valid cannabis club/state program card and/or Health Canada license.
- Healthcare practitioner's statement from another cannabis club/state program or a medical marijuana prescription. (Canadian license holders do not need to submit this)
- Picture identification.
- A signed release of information form so that information can be verified with clubs and state registries. (Health Canada does not have a system for verification.)
- A signed consent form.
- Visitors from the USA must also sign a waiver declaring that any cannabis procured from the dispensary is for their use in Canada only.

Once approved, visitors should be permitted a certain number of visits per year after which they must become full clients (i.e. pay any registration fees and participate in the registration process) in order to access services.

V. CANNABIS SUPPLY

1. Quality of Cannabis

Dispensary clients using medical cannabis may have depleted immune systems or chemical sensitivity. It is essential that medical cannabis dispensed at compassion clubs is free of chemicals, harmful microbiological contaminants, and any other potentially toxic agents.

a. Cultivation

During the cultivation of medical cannabis, caution must be taken to avoid contamination from chemical fertilizers, pesticides and fungicides, as well as potentially dangerous pathogens like yeast, moulds, mildews and fungi. Clubs should strive to offer an organic supply of cannabis with the eventual goal of seeing all Canadian cannabis dispensaries distribute only organic cannabis and by-products.

b. Quality Control

Dispensaries should have quality control standards for raw cannabis, medicated food, tinctures and other cannabis products.

There are several mechanisms to assess quality and to identify problems, including visual and tactile inspection, laboratory testing, and batch numbers. All of these must be used by cannabis dispensaries where relevant and when possible. Ideally, all dispensaries would be able to obtain laboratory data on heavy metals, pesticides and biological impurities. However under the current legal regime there are no labs in Canada licensed to test cannabis for end-users. Organic and Foodsafe certification are also recommended where possible.

2. Cannabis Suppliers

Cannabis cultivators are an integral part of any community-based distribution model. In order to provide a variety of high quality strains to clients at the lowest possible cost, dispensaries have the right to purchase medicine from experienced, dedicated and ethical cannabis cultivators in a secure and confidential manner.

To maintain due diligence around cultivators and production methods and to reduce risk to the cultivator in the climate of prohibition, several protocols should be followed:

a. Contracts

All cultivators should sign a contract with the dispensary. Potential cultivators will participate in a personal interview before receiving a contract, and will agree to supply cannabis only to medical cannabis dispensaries. The contract should be reviewed on a yearly basis.

b. Inspection Protocol

Dispensaries will inspect the contracted cultivation facilities on at least a yearly basis to ensure the cleanliness and safety of the production site and that the scale of the operation does not exceed the amount supplied to the dispensary. The facility will be inspected for plant numbers, integrity of property, safety, cleanliness, air quality, cultivation products and mediums, and the general health of the plants. Any structural damage to property (unless owned by the cultivator) or molds/mildews/fungi are considered unacceptable and may result in termination of contract.

c. Number of Suppliers

Dispensaries will work with as many cultivators as necessary to fulfill the demand for quantity, quality, affordability, and variety of strains.

d. Cultivator Protection

It is imperative that cultivators be legally protected for their part in providing cannabis to those in need. In the meantime, dispensaries will ensure the names of cultivators and the location of their facility is kept confidential. Dispensaries will support cultivators by testifying in court should this be necessary. Cultivators will be given a contract that they can display at their production facility.

(See Section VII (4) for information resources about cannabis cultivation)

VI. GENERAL DISPENSARY RESPONSIBILITIES

1. Accountability and Transparency

In order to ensure that distributors are not accused of profiteering, it is recommended that dispensaries ensure transparency, openness, financial accountability, and mechanisms for client feedback. Non-profit incorporation is one way of meeting these criteria.

2. Applicable Regulations and Laws

Dispensaries must be in compliance with all applicable regulations including: zoning, health and safety codes, labour standards, and WCB employment and reporting requirements.

3. Community Relations

Dispensaries are responsible for any related impact on their neighbours and local communities. It is recommended that they maintain a clean, friendly, well-lit and safe store-front, and have open communication with applicable neighbourhood businesses, organizations, associations, individuals, and social welfare groups.

4. Staffing

a. Training and Experience

Proper staff training is essential to providing effective health care. Areas of staff training should include: the effects of the variety of strains on different symptoms and conditions, dosage, potency, tolerance, dependence, ingestion techniques, side-effects, safe use techniques, potential drug interactions, and visual/tactile quality inspections.

Employees of a cannabis dispensary should have basic first-aid training. Experience with persons with disabilities, and an understanding of poverty and the surrounding issues is also valuable.

b. Legal Understanding

While the legal status of medical cannabis remains in flux, it is crucial that employees fully understand the legal risk they are undertaking to distribute medical cannabis. They should be made aware of their legal rights in the case of arrest.

5. Health and Safety

Dispensaries must maintain a clean and safe environment. All WCB rules and regulations, city by-laws and fire codes must be adhered to. Dispensaries must be clean, follow universal precautions for infection control, and provide

restroom facilities. If there is a smoking-room at the facility, it should be well-ventilated and clients should be cautioned about sharing joints and provided with sanitizing agents for pipes and vaporizers.

6. Accessibility

Ideally, medical cannabis dispensaries should be wheelchair accessible and have a wheelchair accessible washroom. If this proves unfeasible, special arrangements should be made to serve and accommodate the needs of members who use wheelchairs. This could include a home delivery or caregiver pick-up service.

7. Security

In order to provide a safe environment, and to avoid loss or damage to the dispensary, security measures must be taken. Security measures for a medical cannabis dispensary are the same as those necessary to safely and securely operate any business dealing with a valuable product.

Physical measures include: adequate locks, security bars, an alarm system, and a safe for storage of money and cannabis. It is imperative to use discretion when discussing sensitive information, such as the identity and location of suppliers, and details regarding the transportation of cash and cannabis.

8. Privacy and Confidentiality

All of the information provided by clients shall be kept strictly confidential and the dispensary must not release any information about their clients without their written consent. All staff, volunteers, consultants and directors of dispensaries must sign non-disclosure agreements. The dispensary must act in accordance with all relevant privacy regulations.

VII. INFORMATION RESOURCES

1. Background

- A Roadmap to Compassion: http://safeaccess.ca/library/roadmap_to_compassion.pdf
- Senate Special Committee on Illegal Drugs Final Report (recommending that Health Canada license and work with compassion clubs): http://www.parl.gc.ca/common/Committee_SenRep.asp?Language=E&Parl=37&Ses=1&comm_id=85
- BCCCS Operational Standards for the Distribution of Medical Cannabis: http://www.thecompassionclub.org/resources/standardsapr30.pdf

2. Access to Dispensaries

Forms used by the BC Compassion Club Society and the Vancouver Island Compassion Society: they can be used or modified by individual dispensaries.

- http://thevics.com/forms.htm
- http://www.thecompassionclub.org/become/forms

3. Client Education

a. Safe Use

- The BCCCS Safe and Effective Use Pamphlet: http://www.thecompassionclub.org/resources/strainbroch.pdf
- VICS Medical cannabis Guide: http://thevics.com/publications/vics/VICSMedsGuide2005.pdf

b. Countra-indications and drug interactions

- Bayer Canada (distributors of Sativex): http://www.bayerhealth.ca/display.cfm?Object_ID=272&Article_ID=121&expandMenu_ID=53&prevSubItem=5_
- Solvay Pharmaceuticals (maker of the synthetic THC medication Marinol): http://www.solvaypharma.ca/en/products/hcp/pdf/Marinol_HCP_Mono.pdf
- Health Canada: http://www.hc-sc.gc.ca/dhp-mps/marihuana/how-comment/medpract/infoprof/index_rev_e.html

c. Political/Legal Climate

- Canadians for Safe Access: www.safeaccess.ca
- Health Canada's Marijuana Medical Access Division (http://www.hc-sc.gc.ca/dhp-mps/marihuana/index_e.html)
- John Conroy, Q.C. has a comprehensive list of relevant medical cannabis legal challenges and decision in his website's library: http://johnconroy.com/library.html

4. Dispensing Cannabis

Cannabis By-Products and Recipes for Alternative Methods of Ingestion:

- Recipes available at http://thevics.com/vicsdocs.htm

5. Cannabis Supply

Additional Reading and Resources for Safe Cannabis Production:

- Indoor Marijuana Horticulture: The Indoor Bible, by Jorge Cervantes
- Marijuana Indoors: Five Easy Gardens, by Jorge Cervantes
- Marijuana Outdoors: Guerilla Growing, by Jorge Cervantes
- Growing Medical Marijuana Organically, by Jeff Mota, Frieda Weed
- How to Grow Marijuana Indoors for Medicinal Use, by G. W. Carver
- Marijuana Grower's Guide, by Mel Frank, L. P. Kallan (Illustrator), Oliver Williams (Illustrator)
- Indoor Marijuana Horticulture, by Jorge Cervantes
- Ask Ed – Ed Rosenthal's web site: http://www.quicktrading.com/home.html
- Wo/Men's Alliance for Medical Marijuana: http://www.wamm.org/video.htm

6. Additional Information

List of Legal Aid Services (by province):

Commission des services juridiques du Québec	Telephone: (514) 873-3562
Law Society of Nunavut	Telephone: (867) 979-2330
Legal Aid Commission of Newfoundland and Labrador	Telephone: (709) 753-7860 Toll Free: 1-800-563-9911
Legal Aid Manitoba	Telephone: (204) 985-8500 Toll Free: 1-800-261-2960 TTY: (204) 943-1131
Legal Aid New Brunswick	Telephone: (506) 458-8540
Legal Aid Ontario	Telephone: (416) 979-1446 Toll Free: 1-800-668-8258 TTY: (416) 598-8867 TTY: Toll Free: 1-866-641-8867
Legal Aid Prince Edward Island	Telephone: (902) 368-6016
Legal Aid Society of Alberta	Toll-free in Alberta: 1-866-845-3425 Direct from Edmonton (780) 644-7777
Legal Services Board of the Northwest Territories	Telephone: (867) 920-3160, Yellowknife residents only. Toll Free: (888) 920-3160, NWT wide.
Legal Services Society of British Columbia	Tel: (604) 408-2172, Lower Mainland Toll Free: 1-866-577-2525, outside the Lower Mainland
Nova Scotia Legal Aid Commission	Telephone: (902) 420-6578 Toll-free: 1-877-420-6578
Saskatchewan Legal Aid Commission	Telephone: (306) 933-5300 Toll-free: 1-800-667-3764
Yukon Legal Services Society	Telephone: Tel: (867) 667-5210 Toll Free: 1-800-661-0408 ext. 5210