Medical Cannabis
Advisory Group
Queensland

Cannabis for Medical Purposes

Queensland

Proposal for an Amnesty

and interim measures

May 2015

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About the Medical Cannabis Advisory Group QLD

The Medical Cannabis Advisory Group Queensland is a group of patients and carers, family and friends representing patients in Queensland who use cannabis solely for medical purposes. Some of the activities we have undertaken to date and propose to undertake in the future include:

- Proposal for an Amnesty Program
- Proposal for a Medical Cannabis Program for Queensland
- Development of a Sample Cannabis Treatment Plan and Informed Consent Form
- Petition tabled in Queensland Parliament
- Corresponding with State and Federal Parliamentarians and their advisors, Government Departments, health and legal professionals and other stakeholders
- Media interviews
- Facebook group and public information page for patients and carers
- Other papers on patient focused medical cannabis topics
- Surveys and community consultation and feedback

We do not support or condone the use of cannabis for non-therapeutic or recreational use, especially amongst minors, or the diversion of cannabis to the illicit market.

We will be releasing other information papers for patients, carers and interested community members shortly and look forward to working closely with the Queensland Government and being involved in the decision making process on issues that affect the health interests and rights of all patients who need to use cannabis for medical purposes.

Overview: Cannabis for Medical Purposes Law Reform in QLD

Stage One: Amnesty and Interim Measures 2015

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An electronic version of this paper will be available on request for Queensland patients and carers.

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Cannabis for Medical Purposes in Queensland

Background

Currently in Queensland thousands of patients and carers, many with young children are "*out of necessity*" breaking the law and risking criminal prosecution under state criminal laws[1] to access their cannabis either by growing their own or obtaining it from the illicit market.[2]

Many carers are also parents caring for children with life threatening or chronic and disabling medical conditions, and who are also living under the fear and threat of the intervention of child safety services, or the Queensland Police Child Protection and Investigation Unit. These parents and carers are risking a maximum penalty of 25 years imprisonment for the serious offence of aggravated supply of a dangerous drug by administering cannabis to a child under the age of 16.[3]

Patients and carers who are unable to cultivate and produce their own cannabis or cannabis oils are also reliant on the illicit market, and are in many cases being exploited and paying exorbitant prices for goods that are unfit for human consumption.

Patients should not be criminalised by the State and be forced to live under the constant fear and threat of criminal prosecution or suffer needlessly because of their choice of health treatment. Similarly they should not have sanctions or barriers imposed upon them by the Commonwealth or State that prevents them from preserving their health, or having a quality of life and living with dignity and respect.

Patients are already struggling trying to cope with their daily activities and the costs of living with a disability and don't need the further burden and stress of living under the threat of criminal prosecution or trying to source their medicine from criminals. This situation is having a detrimental impact not only on patient's physical and mental health and well-being but also on carers and the family unit as a whole.

The Queensland Government can no longer ignore this important public health issue or the health and welfare of thousands of patients, carers and other family members by leaving them in a situation where they have no choice but to break an unjust law and in doing so risk criminal prosecution rather than die or suffer needlessly. Patients and carers need an immediate exemption from criminal prosecution, and access to support services, including services where they can have their cannabis tested, especially the concentrated oils that are being supplied by parents to their children.

Compassionate Access

Patients all around the world have been turning to cannabis for medical purposes as it has long been proven to be a very effective treatment for serious conditions including epilepsy, MS, cancer, chronic and neuropathic pain and many other conditions. It is also now being recognised and used as an effective treatment for many conditions affecting children including intractable epilepsy, brain tumors and childhood leukemia. It is now available in many overseas jurisdictions including the United States, Canada, Israel, the Netherlands, Spain and several South American countries.

Many patients, carers, medical practitioners, politicians and community organisations have voiced their support for the compassionate use of cannabis for medical purposes where there is clinical justification on the grounds that the standard treatments have either been trialled for appropriate periods of time without sufficient therapeutic benefit, or the standard treatments are not tolerated by the patient or are contraindicated. Whilst conclusive evidence regarding the safety and effectiveness of cannabis has been limited due to the restrictions that have been placed on research, there is an abundance of emerging evidence that many patients have benefited from its use for a range of conditions and symptoms.

[1] *Drugs Misuse Act 1986* (QLD).
[2] See sections 6, 8, 9, 10 & 11.
[3] s 6(2)(a).

The Australian Government and other jurisdictions have acknowledged the benefits of cannabis for medical purposes and that a different approach is needed. Several Bills and schemes have been introduced. These are discussed in more detail below.

Health and Human Rights

In respect to the use of cannabis, it is now widely recognised that the patient, in consultation with his or her doctor, is best placed to determine the individual medical needs of the patient, and that it is the patient that should make the final decision on whether or not to use cannabis - not the State or Commonwealth. One of the most important freedoms patients have when it comes to their health is the fundamental right to choose their own medical care and treatment for any condition representing a harm or danger to their health or quality of life.

This concept has been widely adopted by the courts. In *Rogers and Whitaker*[4] the High Court of Australia stated:

> "the courts have adopted in several cases[5] the principle that while evidence of medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care ***after giving weight to the paramount consideration that a person is entitled to make his own decisions about his life***."[6]

It should be the patient's decision on the form and type of cannabis used, how it's used, duration of treatment, where it is obtained from and if necessary to be able to grow their own as long as they are registered and are not selling it for commercial gain.[7] We therefore stress from the outset that the human and health rights of the patient should be at the centre of any decision making and that any reform measures should have due regard to the rights and liberties of the patients that use cannabis for medical purposes.

Introduction to Medical Cannabis Law Reform for Queensland

This paper proposes that the Queensland Government can lead the nation in cannabis law reform and take action now by introducing an amnesty for patients who are at risk of criminal prosecution by cultivating their own cannabis or obtaining it from the illicit market to enable them to use cannabis solely for medical purposes.

Rather than participate in unnecessary and costly clinical trials run by another State Government, and that are designed to only benefit researchers and drug manufactures, we propose that the Queensland Government can adopt its own policy on the issue and introduce measures that will benefit the State of Queensland and Queensland patients.

Therefore this paper proposes that the Queensland Government change its cannabis policy, and amend subordinate legislation that currently prohibits the use of cannabis for medical and human therapeutic use. This amendment will not only allow for an urgent amnesty that can also be designed to be the basis of a statewide medical cannabis program, but will also enable the Queensland Government to introduce a range of other law reform initiatives to regulate and control the commercial aspect of cannabis for medical purposes in the State of Queensland.

It's time for the Queensland Government to act in the best interests of patients and carers and take all the necessary steps and action required to make cannabis lawfully available for medical purposes in Queensland rather than making patients wait for Commonwealth action or for the Queensland Government to participate in trials conducted by another State Government.

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[4] *Rogers and Whitaker* (1992) 175 CLR 479 at p 487.
[5] See for example *Albrighton v. Royal Prince Alfred Hospital* (1980) 2 NSWLR at pp 562-563; *F v. R.* (1983) 33 SASR 189 at pp 196, 200, 202, 205; *Battersby v. Tottman* (1985) 37 SASR at pp 527, 534, 539-540; *E v. Australian Red Cross* (1991) 99 ALR at pp 648-650.
[6] *F v R* (1983) 33 SASR at p 19.
[7] Professor Penington, *'Medical cannabis: time for clear thinking.'* Med J Aust 2015; 202 (2): 74-75 at https://www.mja.com.au/journal/2015/202/2/medical-cannabis-time-clear-thinking. David G Penington is former Dean of the University of Melbourne's medical school.

We do acknowledge that any proposal to make cannabis lawfully available must strike a balance between a patient's right to choose to use botanical cannabis and the State's responsibility to ensure there are adequate safeguards in place to prevent the diversion of cannabis to the illicit market or access and abuse by minors.

This paper proposes that cannabis for medical purposes should only be available where there is clinical justification for its use and where a patient has in place a cannabis treatment plan; and gives informed consent to his or her doctor assuming full responsibility for the use of the cannabis; and provides an undertaking to Queensland Health by way of a Statutory Declaration that the person will adhere to strict guidelines and conditions.

Whilst provisions in this proposal are patient focused, at the same time the requirements that need to be met for a patient to lawfully access cannabis, are more transparent and rigorous than what is expected from the patients who are accessing cannabis or unapproved cannabis products under other schemes in Australia, including the schemes administered by the Commonwealth Therapeutic Goods Administration.[8]

To be clear any changes for cannabis law reform are not intended to undermine the role of health or law enforcement agencies or the policing of the illicit cannabis market. The scope of reform is to be constrained by specific conditions and safeguards to allow for monitoring, enforcement and investigation powers to ensure the safety of the patient and prevent diversion to the illicit market or misuse by minors.

Queensland Can Lead Australia in Medical Cannabis Law Reform

Queensland can lead the nation in medical cannabis law reform by changing its policy on cannabis and using Queensland's reserved powers under the Constitution to amend subordinate legislation which will allow for regulating powers under existing health legislation to be used to make regulations for the regulation and control cannabis for medical purposes within the State of Queensland.

Queensland is in a unique position to introduce its own medical cannabis law reform measures because it is not constrained by the Commonwealth regulatory framework enacted by the Australian Parliament to comply with international treaties[9] that are binding on the other states and territories that have adopted the Commonwealth health legislation into state law.

The Commonwealth of Australia is a signatory to the Single Convention on Narcotic Drugs 1961 (the Single Convention). As a party to the Convention, the Commonwealth was to limit the use of narcotic drugs exclusively to medical and scientific purposes, because, as the preamble reads, "addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind." At the same time, the Parties recognised "that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and acknowledged that adequate provision ***must*** be made to ensure the availability of narcotic drugs for such purposes…."[10]

The Commonwealth was also required to establish a special administration for the purpose of applying the provisions of the Convention as Commonwealth law,[11] and as far its constitutional limitations would allow to apply throughout its states and territories. The Commonwealth Department of Health, Therapeutic Goods Administration fulfills that requirement by administering a Commonwealth regulatory system of controls under the *Therapeutic Goods Act* 1989 that must provide for the safety, efficacy and timely access to narcotic medicines, which includes cannabis, whilst preventing the abuse and misuse of narcotics.[12]

[8] See for example the Terminally Ill Cannabis Scheme administered New South Wales Health and the Special Access Scheme administered by the Commonwealth Therapeutic Goods Administration.
[9] 1961 Single Convention on Narcotic Drugs
[10] See Article 4 to the 1961 Single Convention on Narcotic Drugs for the full preamble.
[11] See Article 17 - The Parties shall maintain a special administration for the purpose of applying the provisions of this Convention.
[12] A paper discussing the history of the control and regulation of cannabis will be released separately to this paper.

There was an expectation when the *Therapeutic Goods Act* 1989 (Cth) ("the TGA") was passed that each State and Territory would pass complementary legislation. Other than Western Australia and Queensland all other states and territories enacted legislation that adopted the TGA as state law.[13] New South Wales and Victoria also enacted provisions that automatically update state law in accordance with the TGA.[14]

Due to constitutional limitations, the TGA only applies to corporations and entities in Queensland that trade interstate or export and import drugs. It does not apply to sole traders, small business or cooperatives registered under Queensland law and trading within the State of Queensland.

Today Queensland still has in place state health legislation with adequate regulating powers and prescribing standards that are in the public interest, and that will allow for, the safe and effective regulation and control of all aspects of cannabis for medical purposes in Queensland.[15]

History of Opposing Commonwealth Health Standards

The Queensland Government has a long history of being opposed to Commonwealth health standards that are not adequate or in the public interest for Queensland. On 3 June 1952, then of Queensland, Vince Gair responded to the Prime Minister's request for Queensland to adopt national standards, and noted the limitations of the Commonwealth's powers to the importation and exportation of therapeutic substances. In reply Premier Gair indicated that Queensland would be represented at a National Health Conference but continued:

"You will understand that any recommendations made by the conference will not necessarily be accepted by my Government. Under no circumstances will this State agree to the acceptance of uniform standards which are not considered to be adequate in the public interest ..... I mention that there is power under the existing Health law of this state to prescribe standards for therapeutic substances, and insofar as Queensland is concerned fresh legislation would not be required."[16]

Although the Commonwealth has in place schemes that allow for limited patient access to cannabis and cannabis products there are so many bureaucratic barriers in place the schemes themselves are prohibitive to most patients and are not in the public interest.

Current Review of Queensland Health Legislation to Adopt Commonwealth Law

In September 2014 the Queensland Health Department presented a Bill for limited community consultation that will provide for the TGA to be adopted as a law of Queensland. At present an individual or business holding a manufacturing licence under the TGA is also required to apply for a license under the Queensland legislation. Under the Bill these manufacturers will only be required to register their business with the Director-General.[17]

However full adoption of this Bill would place Queensland patients in a similar situation as patients in the other states that have adopted the TGA, as these states and territories are restricted to the TGA and conducting research trials in accordance with the Commonwealth legislation, or are required to introduce new legislation and make complex amendments to other legislation. The adoption of the TGA by the other jurisdictions has left patients in a situation where they will be waiting years for clinical trials to be conducted or for an affordable supply of cannabis products manufactured by drug companies to be approved by the Therapeutic Goods Administration and the Pharmaceutical Benefits Scheme.

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[13] Regulation 3 of the *Therapeutic Goods Regulations 1990 - Poisons and Therapeutic Goods Act 1966* (NSW); *Poisons and Therapeutic Goods Regulation 2008* (NSW); *Therapeutic Goods (Victoria) Act 2010* (Vic); *Controlled Substances Act 1984* (SA); *Controlled Substances (Poisons) Regulations 2011* (SA); *Therapeutic Goods Act 2001* (Tas); *Therapeutic Goods Regulations 2002* (Tas); *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT); *Medicines, Poisons and Therapeutic Goods Regulation 2008* (ACT).

[14] Therapeutic Goods Administration, Commonwealth of Australia publication, *'A History of Therapeutic Goods Regulation in Australia,'* John McEwan at p 169.

[15] The *Health Act* 1937 (QLD) and *Health (Drugs and Poisons) Regulation* 1996 (QLD).

[16] Therapeutic Goods Administration, Commonwealth of Australia publication, 'A History of Therapeutic Goods Regulation in Australia,' John McEwan at p 20.

[17] Regulatory Policy Unit, Department of Health, '*Overview - Consultation draft of Medicines, Poisons and Therapeutic Goods Bill 2014'.*

Patients in Queensland, or for that matter all patients in Australia, should not have to wait years for trials to be conducted; or for cannabis products to be approved by the TGA and commercially available from overseas drug manufacturers or local suppliers; or go through the complex TGA access schemes; or wait for the Commonwealth to enact separate legislation to the TGA to allow for the commercial production of cannabis, and if passed the new Commonwealth legislation would need to be adopted in Queensland law in any case.

Brief Overview of Law Reform Measures

We propose that amendments should be made to the *Drugs and Poisons Regulation* to allow for the medical, scientific and human therapeutic use of cannabis, and that further amendments be made pursuant to existing regulating powers of the *Health Act* to allow for the regulation and control of cannabis for medical purposes within the State of Queensland, and for a range of other measures to be introduced.

Regulation 270A of the *Health (Drugs and Poisons) Regulation 1996* (QLD) [18] currently provides that "the Chief Executive Officer must not grant an approval to a person to manufacture, obtain, possess or use a S9 poison for human therapeutic use."

A change to Government policy to approve the amendment of regulation 270A to allow for the medical and human therapeutic use of cannabis, cannabis resin and cannabis products would also provide an opportunity for the Queensland Government to foster the emerging cannabis industry in Queensland.

We propose that law reform measures could be implemented over four stages or concurrently as follows:

1. An urgent amnesty from criminal prosecution for qualifying patients and carers who are cultivating, producing, supplying or possessing cannabis for the patient to use solely for medical purposes, and access to state services for testing of cannabis oils and a range of interim measures to access quality controlled oils from overseas suppliers until a local source is available.

2. A state-wide medical cannabis program with a photo identification card system, and the appointment of an independent advisory panel, and adequate education, training and other support services

3. The commercial production of cannabis and cannabis products for wholesale supply to pharmacies and dispensaries, and

4. The establishment of cannabis research and information centres, research trials and academic scholarships and other measures.

The Queensland Government has an opportunity to act in the interests of Queensland patients now and into the future by also supporting small business, farmers and other stakeholders who are interested in ensuring that patients have a guaranteed supply of quality controlled cannabis and cannabis oils.

Overview: Legislative Framework

Commonwealth

The Commonwealth has primary control of the regulatory system with a division of responsibility between the Commonwealth and the States and Territories broadly broken down as:

- Commonwealth regulates and prescribes standards for the importation and exportation and commercial availability of therapeutic substances in Australia and the licensing of drug manufacturers under the *Therapeutic Goods Act 1989*. As mentioned above, Queensland and Western Australia have not adopted the TGA into state law.[19]

[18] See Regulation 270A of the *Health (Drugs and Poisons) Regulation* 1996.
[19] See Regulation 3 of the *Therapeutic Goods Regulations 1990* (Cth) for corresponding state and territory legislation.

- The States regulate the production, cultivation, sale, supply, possession, handling and use of drugs and poisons under state health and criminal legislation.

Commonwealth Poisons Standard 2014

The Commonwealth Poisons Standard 2014 is made under *Therapeutic Goods Act 1989*[20] and consists of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the SUSMP). The SUSMP is a compilation of decisions made by the Secretary of the Department of Health, or the Secretary's delegate[21] regarding the classification of poisons into Schedules as ***recommendations*** only to Australian States and Territories for implementation through relevant State and Territory legislation.[22]

The SUSMP is presented with a view to promoting uniform:

- scheduling of poisons throughout Australia;
- signal headings on labels for poisons throughout Australia;
- labelling and packaging requirements for poisons throughout Australia;
- additional controls on the availability and use of poisons in Australia.

Poisons are not scheduled on the basis of a universal scale of toxicity. Although toxicity is one of the factors considered, the decision to include a substance in a particular Schedule should also take into account many other criteria such as:

- the purpose of use
- potential for abuse
- safety in use, and
- the need for the substance.

Poisons are classified according to the Schedules in which they are included using their approved names[23] wherever practicable. For the legal definition it is necessary to check with each relevant State or Territory authority. The scheduling classification sets the level of control to be exercised over the availability of poisons as ***recommended by*** the Health Secretary or the NCCTG to the States and territories.[24]

The TGA and Cannabis and Cannabis Products

Cannabis is listed in Schedule 9 of the SUSMP (except where listed separately[25]) as a prohibited substance that may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law *except* when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth *and/or* State or Territory Health Authorities.[26]

Although it is not widely publicised or understood, the TGA already contains provisions that will allow for patient access to unapproved medicines including cannabis, cannabis resin and cannabinoid products for experimental and special use in circumstances where there is clinical justification and no registered supply available.[27] However this system is complex and costly and has so many barriers that very few patients are able to access cannabis through these mechanisms as most medical practitioners are unwilling to use it. These mechanisms are discussed in more detail at the end of this paper.

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[20] See s 52D(2) *Therapeutic Goods Act 1989* (CTH). The SUSMP should be read in conjunction with the *Framework* (SPF *Scheduling Policy*).
[21] The National Coordinating Committee on Therapeutic Goods (NCCTG).
[22] See s 52D and Poisons Standard 2014, page iii.
[23] Cannabis (common name hashish) is listed as a herbal substance in the Australian Approved Name Index (AAN). See TGA Approved Terminology for Medicines, Section 3 – Herbal Substances, July 1999 at pg 359. See also the Australian Chemical Name Index, the International Non-Proprietary Name (INN) Index and US Adopted Name Index for cannabinoid substances.
[24] Other Commonwealth Acts, legislative instruments and other documents, which integrate with the SUSMP, include the *Therapeutic Goods Regulation 1990*, Therapeutic Goods Order 69 - *General requirements for labels for medicines*, Therapeutic Goods Order 80 - *Child-Resistant Packaging Requirements for Medicines* and the *Required Advisory Statements for Medicine Labels* (RASML).
[25] See Schedules 4 and 8; or processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.
[26] SUSMP 2015 at p 217.
[27] See section 19 of the TGA - Special Access Scheme, Authorised Prescribers, Personal Importation and Clinical Trials.

TGA Scheduling of Cannabinoids – cannabidiol, nabiximols, and dronabinol

The TGA have recently made a new entry in Schedule 4 of the SUSMP for *cannabidiol* (CBD) in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis.[28] To date there are no registered products on the ARTG.[29] However patients may be able to access unapproved products through the SAS or if they have a valid prescription import the product lawfully from overseas sources under the Commonwealth Personal Importation Scheme until a local supply source is available.

Nabiximols (THC and CBD)[30] and *dronabinol* (delta-9-tetrahydrocannabinol)[31] are listed in Schedule 8 of the SUSMP. These manufactured cannabinoids have additional controls on possession or supply pursuant to Appendix D, which provide that these substances are available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health and Ageing under section 19 of the *Therapeutic Goods Act 1989*. Dronabinol (a synthetic form of THC approved by the FDA) is also subject to Appendix K and is required to be labelled with a sedation warning.[32]

Sativex

On 2 December 2013, Sativex containing the active ingredient nabiximols was approved as a new chemical entry on the ARTG.[33] In July 2013 the Pharmaceutical Benefits Advisory Committee (PBAC) rejected a submission filed by Novartis Pharmaceuticals Australia Pty Limited seeking listing of nabiximols marketed under the registered trade name of Sativex for the treatment of moderate to severe spasticity due to multiple sclerosis in a patient who is intolerant to anti-spasticity medication and/or has not adequately responded to anti-spasticity medication.[34]

Queensland Criminal Legislation

In Queensland the Minister for Police administers the *Drugs Misuse Act 1986 (QLD)* (the "DMA") and the regulations. From the outset it should be noted that the reports of the introduction of and debate on the Drugs Misuse Bill 1985 made no mention of its effect overriding common law health and human rights, and for all intents and purposes was not to apply to the actual users of drugs. In his second reading speech the Honourable W.H. Glasson stated:

> "The Drugs Misuse Bill was introduced under tough new measures to combat drug trafficking in Queensland ... quite contrary to what some media commentators have stated and printed over the last week, the principal thrust of the Bill is not aimed at actual users of drugs…. the Bill is aimed at protecting our young people from the greed of those who live off the drug habits that their unfortunate victims develop. Drug-traffickers in this filthy trade and I do not care who they might be are nothing but parasites on today's young people and society in general, extracting millions of dollars from those who are addicted. These are the people that this Bill is intended to catch not their victims. By the introduction of this Bill it is intended to make Queensland a most unpopular place, in fact the most unpopular place in Australia for hard drug dealers or traffickers… "[35]

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[28] Therapeutic Goods Administration, ACMS, Reasons for the medicines scheduling delegates final decisions, 19 March 2015 (Medicines) at https://www.tga.gov.au/book/part-final-decisions-matters-referred-expert-advisory-committee-2.

[29] The United Kingdom based company GW Pharmaceuticals are conducting trials in the United States and are not expecting to submit a new drug application with the FDA for approval of its CBD cannabinoid medicine until the middle of next year.

[30] Nabiximols are described as botanical extracts of *Cannabis sativa* which include the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use at in Schedule 8 of the SUSMP at pp 214-215.

[31] SUSMP 2015 at p 214.

[32] SUSMP 2015 at pp 288-90. Dronabinol is marketed by Solvay Pty Ltd under the trade name of Marinol.

[33] See the Public Assessment Report for nabiximols in an oral spray, 10 mL (90 actuations of 100 microlitres), the Therapeutic Goods Administration website at https://www.tga.gov.au/auspar/auspar-nabiximols.

[34] The application was rejected on the basis of insufficient evidence to establish comparative effectiveness and safety compared with standard care alone in patients who are intolerant to anti-spasticity medication; and no evidence of efficacy and safety provided in comparison with high dose baclofen alone, or in combination with dantrolene or diazepam as the second-line therapy. See the Commonwealth Department of Health, PBS Public Summary Document at http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/nabiximols.

[35] Honorable H.W. Glasson, Drugs Misuse Bill, Note 14, pp 3472-3481.

Offences

There are several offences in the DMA that may apply to a person who uses cannabis for medical purposes, and carers, many whom are parents of children under the age of 16. A person may be found guilty of an offence if the person *unlawfully* carries out any of the following:

- trafficking in dangerous drugs[36]
- supplying dangerous drugs[37] includes the offence of aggravated supply of cannabis to a minor under 16 years of age[38]
- producing dangerous drugs[39] includes cultivation, manufacture or production of cannabis, cannabis resin or cannabinoids
- publishing or possessing instructions for producing dangerous drugs[40]
- possession of dangerous drugs[41]
- possessing things[42] including possessing things used to administer, cultivate or produce cannabis or cannabinoids
- permitting use of place[43] includes permitting use of place to produce, cultivate or supply cannabis.

Harsh penalties can apply including a maximum penalty of 25 years imprisonment for the offence of aggravated supply of a dangerous drug by administering cannabis to a child under the age of 16.[44] Most matters not involving commercial quantities or where there is no evidence of trafficking may be heard in the Magistrates Court.

First time offenders who plead guilty may be offered drug diversion, and in other cases a fine, community service or a suspended sentence. In many cases no conviction may be recorded, however the charge itself can impact on a person, for example some areas of employment, or when applying for a visa to some countries, where both charges and convictions must be declared.

Legal Duty of Carers and Legal Guardians

In Queensland the Criminal Code[45] also provides for a number of legal responsibilities and duties that may apply to a carer or legal guardian who may be left with no alterative but to provide a patient under their care with medical cannabis out of necessity to prevent harm or danger to life or health.

For example section 285 provides for the duty to provide necessaries: "It is the duty of every person having charge of another who is unable by reason of age, sickness, unsoundness of mind, detention, or any other cause, to withdraw himself or herself from such charge, and who is unable to provide himself or herself with the necessaries of life, whether the charge is undertaken under a contract, or is imposed by law, or arises by reason of any act, whether ***lawful or unlawful,*** of the person who has such charge, to provide for that other person the necessaries of life; and the person is held to have caused any consequences which result to the life or health of the other person by reason of any omission to perform that duty."

Section 286 provides for the necessaries of life for the child: "It is the duty of every person who has care of a child under 16 years to provide the necessaries of life for the child; and take the precautions

[36] s 5 of the *Drugs Misuse Act* 1986 (QLD)
[37] s 6
[38] ss 6(2)(a)
[39] s 8
[40] s 8A
[41] s 9
[42] s 10
[43] s 11
[44] s 6(2)(a)
[45] Criminal Code 1899 (QLD).

that are reasonable in all the circumstances to avoid danger to the child's life, health or safety; and take the action that is reasonable in all the circumstances to remove the child from any such danger; and he or she is held to have caused any consequences that result to the life and health of the child because of any omission to perform that duty."

Section 324 provides for the failure to supply necessaries: "Any person who, being charged with the duty of providing for another the necessaries of life, without lawful excuse fails to do so, whereby the life of that other person is or is likely to be endangered or the other person's health is or is likely to be permanently injured, is guilty of a misdemeanor, and is liable to imprisonment for 3 years."

Defences

In the DMA, the definition of *unlawfully* is given the statutory meaning *"without authorisation, justification or excuse by law."* The Criminal Code 1899 (QLD) applies to the DMA[46] and contains provisions for the defence of *justification and excuse – compulsion*[47] and the defence of extraordinary emergencies.[48]

It is clear from the definition of unlawfully that parliament has not abrogated the important common law defence of necessity or the defence of extraordinary emergencies[49] and in the context of its use in the DMA and the Criminal Code, *unlawfully* implies that in certain circumstances, the law may excuse a person from criminal prosecution.

However the availability of a defence, does not preclude a person from being charged in the first instance. Unless a police officer uses discretion not to arrest or charge a person, or the Director of Public Prosecutions makes a decision not to prosecute the matter on public interests grounds[50] or because of lack of evidence, a person charged with a criminal offence is required to raise a defence in his or her Court proceedings.

This involves a criminal hearing or trial, which is a lengthy, complex and burdensome process. To successfully raise a defence, a person would be required to produce expert testimony from the person's doctor, which can be quite costly, and in many cases, while doctors are prepared to provide a written report or letter for his or her patient, most are unwilling to provide an expert affidavit and attend Court to give expert evidence.

Furthermore, while both defences are available in law,[51] there are no recorded cases involving cannabis as these matters are generally heard in the lower courts.[52] Similarly, in the majority of cases involving cannabis charges, a guilty plea is entered, and the use of cannabis for medical purposes is only raised as a mitigating factor on sentencing, and the person given a fine; or a bond or suspended sentence; and in some circumstances both.

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[46] s 116

[47] s 31(1)(d) provides "A person is not criminally responsible for an act or omission, if the person does or omits to do the act under any of the following circumstances, that is to say when (i) the person does or omits to do the act in order to save himself or herself or another person, or his or her property or the property of another person, from serious harm or detriment threatened to be inflicted by some person in a position to carry out the threat; and (ii) the person doing the act or making the omission reasonably believes he or she or the other person is unable otherwise to escape the carrying out of the threat; and (iii) doing the act or making the omission is reasonably proportionate to the harm or detriment threatened."

[48] s 25 provides "Subject to the express provisions of this Code relating to acts done upon compulsion or provocation or in self-defence, a person is not criminally responsible for an act or omission done or made under such circumstances of sudden or extraordinary emergency that an ordinary person possessing ordinary power of self-control could not reasonably be expected to act otherwise."

[49] This contention is consistent with the important and well-established principle of statutory interpretation, affirmed by the High Court in *Daniels Corp* v *ACCC* [2002] HCA 49 at 11 per Gleeson CJ, Gaudron, Gummow and Hayne JJand referred to with approval by the Queensland Court of Appeal in *Meredith v State of Queensland* [2006] QCA 465 per McMurdo P at 3; Kean JA at 17. See also *Re Bolton, Ex parte Beane* (1987) 162 CLR 514 at 523 per Brennan J; *Bropho v Western Australia* (1990) 171 CLR 1 at 18 citing *Potter v Minahan* (1908) 7 CLR 277 at 304.

[50] See Office of the Director of Public Prosecutions, Department of Justice and Attorney General, 'Directors Guidelines', pp 1-5. The Directors Guideline's can be viewed at http://www.justice.qld.gov.au/__data/assets/pdf_file/0015/16701/Directors-guidelines.pdf.

[51] For cases involving the necessity defence see *R v Loughnan* [1981] VR 443 at [448]; *R v Cairns* [1999] 2 Crim App Rep 137 1981] VR 443 at [448]; and *R v Rogers (1996)* 86 A Crim R 542.

[52] T Bogdanoski, in *"A Dose of Human Rights: An Antidote to the criminal prohibition of cannabis for medical use?* (2009) 33 Crim LJ 251 cites several cases in the Lismore District Court where the defense was successfully raised. In 1991 a fine of $500 was overturned involving the cultivation of 6 cannabis plants; and in 1999 a fine and conviction were overturned after the defence had been raised by a patient with lymphoma who had used cannabis for unresolved pain and suffering.

Brief Overview: Necessity Defence

The English Courts introduced the concept of necessity as early as 1551. *In Reninger v Fagossa*[53] the court stated that:

> "A man may break the law, and yet not break the law itself …. where the words of them are broken to avoid a greater inconvenience, or through necessity, or by compulsion."[54]

In 1765 William Blackstone recognised that the necessity defence was founded upon the theory that individuals should not be punished when they are not acting out of free will and that "the law ought to promote the achievement of higher values at the expense of lesser values, and that sometimes the greater good for society will be accomplished by violating the literal language of the criminal law."[55] Blackstone also described a common law right to bodily integrity as including "a right to the preservation of a man's health from such practices as may prejudice or annoy it."[56]

In Australia the necessity defence has been articulated in several cases,[57] and in Queensland referred to in cases involving the defense of extraordinary emergency, however there are no recorded cases where it has been successfully raised in relation to the cultivation or possession of cannabis.[58]

United States – Medical Cannabis Cases

In 1976, *US v Randall*[59] was the first legal case in the Untied States to bring about change to drug policy, and to extend the necessity defence to the crimes of possession or cultivation of cannabis. Robert Randall began smoking cannabis after conventional drugs proved ineffective in treating his glaucoma. In 1975 Randall was arrested and charged with possession of "marijuana."[60]

In response to Randall's assertion of the medical necessity defence, the Court recognised its responsibility to set forth clearly and in some depth its understanding of the applicable law. In finding that the necessity defence was available to Randall, the Court set forth the requisite elements of the defense as follows: the defendant did not intentionally bring about the circumstances that precipitated the unlawful act; the defendant could not accomplish the same objective using a less offensive alternative; and that the evil sought to be avoided was more heinous than the unlawful act perpetrated to avoid it.

The D.C. Superior Court accepted Randall's necessity submission, which included extensive medical evidence and testimony. The Court balanced Randall's interest in his health against the state's interest in enforcing drug laws that protect the public and concluded that Randall's right to preserve his sight outweighed the state's interest in outlawing the drug. Consequently the Court held that Randall was "not guilty" of the crime of the possession of marijuana.

In 1978, federal agencies, disquieted by Randalls' outspoken opposition to the medical prohibition, sought to silence him by disrupting his legal access to marijuana. In response, Randall brought suit against the FDA, DEA, NIDA, the Department of Justice and the Department of Health, Education & Welfare. Twenty-four hours after the suit was filed, federal agencies requested an out-of-court settlement, which resulted in the provision to Randall with prescriptive access to marijuana through a federal pharmacy located near his home making him the first legal medical cannabis smoker in the United States since 1937.

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[53] [1551] 1 Plowden, 75 English Reports..
[54] See also Criminal Code 1899 QLD ss 22 and 31(1)(d).
[55] See William Blackstone, Commentaries on the Laws of England at p 28.
[56] Ibid at p 134.
[57] For cases involving the necessity defence see *R v Loughnan* [1981] VR 443 at [448]; *R v Cairns* [1999] 2 Crim App Rep 137[1981] VR 443 at [448]; and *R v Rogers (1996)* 86 A Crim R 542.
[58] See for example *R v Patel* (No 7) [2013] QSC 65; *Carter v Attorney General for the State of Queensland* [2013]; QCA 140; *Wilkinson v Stevenson* [2000] QDC 426; *State of Qld v Alyssa Nolan & Anor* [2001] QSC 174; *Moores v Pearce* [2013] QDC 32.
[59] *United States v. Randall,* No. 65923–75, D.C. Superior Court (24 Nov 1976), reprinted in 104 Daily Washington Law Reporter 2249-54 (1976); See also *Jenks v. State*, 582 So.2d 582-680 (Fla. Dist. Ct. App. 1991; *United States v. Oakland Cannabis Buyers' Coop*., 190 F.3d 1099-1111 (9th Cir. 1999).
[60] The United States *Marihuana Tax Act of 1937* legitimized the use of the term "marijuana" as a label for hemp and cannabis plants and products in the US and around the world. Prior to 1937, "marijuana" was slang; it was not included in any official dictionaries and is probably of Mexican origin. See Wikipedia at http://en.wikipedia.org/wiki/Marihuana_Tax_Act_of_1937.

The settlement became the legal basis for the FDA's Compassionate IND program. Initially, this program was limited to patients afflicted by marijuana-responsive disorders and some orphan drugs however, in the 1980's the concept was expanded to include HIV-positive people seeking legal access to drugs, which had not yet received final FDA marketing approval. This system is similar to the schemes administered by the Commonwealth Therapeutic Goods Administration.

Following Randall, the necessity defence has been used in State Courts across the United States paving the way for significant reform.[61] In some cases a fourth element of the defence was raised, in that there were no other legal alternatives for the defendant, however the Courts denied an argument raised by the prosecution, that a defendant should advocate for the laws to be changed.[62]

In the United States over 23 States have now passed state legislation that allows for cannabis and cannabis products to be available for patient access through various avenues within those State's jurisdiction. Depending on the State legislature, patients can access cannabis either by growing it himself or herself, or by nominating a carer or a cooperative to cultivate it for them, or by purchasing it through a licensed dispensary or direct from large-scale commercial cultivators.

Queensland Health Legislation

The *Health Act* contains a number of regulating powers about drugs, articles, substances and things and about monitoring, investigation and enforcement. Two pieces of subordinate legislation containing the current regulations for medicines and poisons in Queensland are contained within:

- The *Heath (Drugs and Poisons) Regulation 1996* (QLD) (the "*Drugs and Poisons Regulation")* which provides for a comprehensive range of controls over the manufacture, possession, prescription, dispensing, administration, and use of drugs and associated activities.

- The *Health Regulation* 1996 (QLD) sets out standard operating procedures for dispensing and dispensaries and imposes controls over the advertising, promotion and labelling of therapeutic substances.

Current Prohibition on s9 Drugs for Human Therapeutic Use

Regulation 270A of the *Drugs and Poisons Regulation* currently provides that "the Chief Executive Officer must not grant an approval to a person to manufacture, obtain, possess or use a S9 poison for human therapeutic use."

Section 77 – dronabinol (*delta*-9-tetrahydrocannabinol (THC)

Section 77 of the *Drugs and Poisons Regulation* provides that a person must not dispense, prescribe, sell or use dronabinol unless the person is a doctor, or a member of a class of doctors, approved for the purpose and dispenses, prescribes, sells or uses the drug under the approval; or is a pharmacist and dispenses dronabinol on the prescription of a doctor who has an approval to prescribe it. Dronabinol is a FDA approved synthetic form of THC marketed by Solvay Pty Ltd under the trade name of Marinol.

Cannabidiol and Nabiximols

There are currently no provisions in the *Drugs and Poisons Regulation* to allow for the Chief Executive Officer to grant a person approval to be authorised to dispense, prescribe, sell or use cannabidiol or nabiximols. GW currently has a form of nabiximols marketed under the trade name of Sativex.

Regulating Powers and Prescribing Standards

Section 180 (1) of the *Health Act 1937* provides that the Governor in Council may make regulations under this Act.

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[61] See also *Jenks v. State*, 582 So.2d 582-680 (Fla. Dist. Ct. App. 1991; *United States v. Oakland Cannabis Buyers' Coop*., 190 F.3d 1099-1111 (9th Cir. 1999).

[62] In *United States v. Oakland Cannabis Buyers' Coop*., 190 F.3d 1099-1111 (9th Cir. 1999) the court added a fourth element in that there were no legal alternatives.

Amongst a raft of other regulating powers in Part 4 of the *Health Act* about drugs including manufacturing, packaging and labeling requirements and advertising,[63] the Act also provides that a regulation may be made about the following matters:

- prescribing standards for the composition, strength, weight, quantity, purity, or quality of any drug or article, or of any ingredient or component part thereof, or for the nature or proportion of any substance which may be mixed with or used in the preparation or preservation thereof, or prohibiting the addition of any article to any drug or article;[64]

- defining or prescribing poisons or restricted drugs or controlled drugs or biological preparations;[65]

- regulating and controlling and, as deemed necessary, prohibiting or restricting the ownership, possession, manufacture, cultivation, sale, distribution, supply, use, lending, dispensing, prescribing, or giving away of, or forging and uttering of prescriptions for or any other dealing with poisons, restricted drugs, controlled drugs, biological preparations …… or goods for therapeutic use[66] under and within the meaning of the *Therapeutic Goods Act 1989* (Cth).[67]

Monitoring, Investigation and Enforcement

Part 4A of the *Health Act* contains a raft of provisions that provide for regulations to be made about monitoring, investigation and enforcement including the appointment of inspectors, appointment conditions and limits on power, identity cards, powers of inspections including entry of places, search and seizure, stopping motor vehicle, power to seize, and power to obtain information and warrants.[68]

Proposal to Amend Subordinate Health Legislation

We propose that the Queensland Executive Council change its policy in relation to the use of cannabis, and use the State's reserved powers on the matter, and make amendments to subordinate legislation that will allow for the regulation and control of cannabis for "medical purposes" to come under the responsibility of the Queensland Minister for Health, rather than under the criminal legislation and the Minister for Police, or under Commonwealth standards and control.

Amendment to Regulation 270A - Human Therapeutic Use of Cannabis

To achieve this we propose that the following amendments be made to the health legislation that will allow for an amnesty, medical cannabis program and other law reform initiatives to be introduced in Queensland as follows:

The Governor in Council make an amendment to regulation 270A of the *Health (Drugs and Poisons Regulation) 1996* pursuant to section 180(1) of the *Health Act 1937,*[69] to read as follows:

> *The Chief Executive Officer of Health may grant an approval to a person to be authorised to cultivate, produce, manufacture, supply, possess, obtain and use botanical cannabis, cannabis resin and cannabinoids for medical, scientific and human therapeutic use.*

Cannabidiol and Nabiximols

Insert new provisions in the *Drugs and Poisons Regulation* to allow for the Chief Executive Officer to grant a person approval to be authorised to manufacture, produce, dispense, prescribe, sell or use products containing the active ingredients cannabidiol or nabiximols.

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[63] *Health Act 1937* (QLD) s 101 - 133
[64] s 132(a)
[65] s 132(t) of the *Health Act 1937* (QLD).
[66] *Therapeutic Goods Regulations* 1990 section 3 provides that *therapeutic use* means use in or in connection with preventing, diagnosing, *curing or alleviating a disease*, ailment, defect or injury in persons; or influencing, inhibiting or modifying a physiological process in persons; or testing the susceptibility of persons to a disease or ailment;…
[67] s 132(u) of the *Health Act* (QLD)1937.
[68] ss 134 - 153
[69] *Health Act* 1937 180 (1)

To make any other amendments to legislation that is deemed necessary to allow for the medical, scientific and human therapeutic use of cannabis, cannabis resin and cannabinoids in the State of Queensland.

Exemption: *Drugs Misuse Act*

The amendment to Regulation 270A will allow for the principle of authorisation to be used as the underlying legal concept to allow an eligible person to be granted approval to be authorised to '***lawfully***'[70] undertake activities which would otherwise be an offence under the *Drugs Misuse Act* by providing an authorised person with an exemption from criminal prosecution.

This concept avoids enacting new legislation or major amendments to the offences, penalties and Schedules in the *Drugs Misuse Act,* or changes to other substantive legislation that could potentially hold up or draw out the implementation of an amnesty and medical cannabis program. This will also bring the regulation and control of cannabis for medical purposes rightly under the health legislation and the responsibility of the Health Minister, rather than the criminal legislation and the Minister for Police. It will also avoid confusion with existing provisions in the *Drugs Misuse Act* that allow for the commercial production of industrial cannabis.[71]

The amendment will also allow for the introduction of a number of cannabis law reform initiatives that are discussed in more detail below.

Application of Commonwealth and Interstate Law

- The Commonwealth Poisons Standard under the *Therapeutic Goods Act* 1989 (Cth) and regulations will not apply to cannabis, cannabis resin and cannabis oils and tinctures regulated and controlled within the State of Queensland under new provisions of the *Drugs and Poisons Regulation*.[72]

- Cannabinoids scheduled as s4[73] and s8 prescription only medicines approved for therapeutic use under provisions of the *Therapeutic Good Act* (Cth) will continue to be regulated, controlled and prescribed under provisions of that Act and under the regulations that they are currently regulated and controlled under in the *Drugs and Poisons Regulation*.

- The import, export and interstate trade of cannabis, cannabis resin and cannabinoids will continue to be regulated under the *Therapeutic Goods Act 1989* (Cth), *Customs Act 1901* (Cth) and other Commonwealth legislation.

- The intrastate regulation and control of cannabis, cannabis resin and cannabinoids in the other states and territories will continue to be the responsibility of those jurisdictions.

Cannabis Law Reform Measures for Queensland

We propose that the above mentioned amendment to Regulation 270A of the *Drugs and Poisons Regulation,* and any other amendment deemed necessary to allow cannabis, cannabis resin and cannabinoids to be used for medical, scientific and human therapeutic use, will also allow for a range of regulations to be made about the following matters:

[70] The DMA provides that unlawfully means without "*authorisation, justification or excuse by law.*'
[71] See s 4a and Part 5B of the *Drugs Misuse Act*.
[72] Therapeutic Goods Administration, *Commonwealth Poisons Standard* 2015.
[73] See the Therapeutic Goods Administration, ACMS, *'Australian Public Assessment Report: Nabiximols,'* 2 December 2013 at https://www.tga.gov.au/auspar/auspar-nabiximols; ACMS 'Reasons for the medicines scheduling delegates final decisions, March 2015 (Medicines) Cannabidol, '19 March 2015 at https://www.tga.gov.au/book/part-final-decisions-matters-referred-expert-advisory-committee-2.

Stage 1: Amnesty and Interim Measures

Insert a new part in the *Drugs and Poisons Regulation* pursuant to provisions in Part 4 and Part 4A of the *Health Act* or use discretionary power if available to introduce adequate regulations therein about the following as a matter of urgency:

- *Granting of an Amnesty*

  To allow for qualifying patients, carers or nominated carers to register under an amnesty program to be granted protection from criminal prosecution for carrying out specified permitted activities that would otherwise be an offence under the *Drugs Misuse Act* until further amendments are made to the health legislation that will allow for them to be granted approval to be authorised to continue the permitted activities under the provisions of a regulated and controlled statewide photo identification medical cannabis program.

- *Appointment of an Expert Panel - Processing of Applications*

  The appointment of an expert panel comprising of doctors, patient advocates, health inspectors and law enforcement officials and other key stakeholders to process the amnesty applications, and to facilitate the introduction of the interim measures as a priority.

- *Appointment of a Steering Committee*

  The appointment of a steering committee comprising of qualified people, patient advocates and other key stakeholders for the purpose of overseeing amendments to legislation to allow for the introduction of cannabis for medical purposes in the State of Queensland.

- *Access to Analytical Laboratories*

  In the interests of the health and safety of patients and to assist them in making informed choices we propose that Queensland Health make available the State Analytical Services[74] to patients and carers to test samples their cannabis and cannabis oils for potency, heavy metals, homogeneity, solvents, microbes, mold, pesticides and other contaminants. Access to the laboratories will also assist an emerging industry in the research and development of strains and cannabis products.

  This service has been available throughout the United States for almost a decade. For example SC Laboratories in California is one of the first independent analytical institutions to recognize the importance of promoting cannabis safety through education, testing and certification and provides a comprehensive testing array for pesticide and microbiological contamination as well as potency analysis.[75]

  PhytaLab is the original Washington cannabis testing facility that has set the standard for Good Laboratory Practice in the *Cannabis* industry. PhytaLab chemical tests are based on Bioanalytical Method Validation for accuracy and precision. They offer a range of services for growers, producer/processors and retail facilities and can provide State Certified Testing with Certificate of Analysis delivery within 2-4 days. PhytaLab also offers consulting services to business and regulatory entities. Founder and Chief Science Officer, Dr. Sexton helped to "write the book" on analytical testing for *Cannabis*, the American Herbal Pharmacopoeia Cannabis Monograph.[76]

  Steep Hill opened the first commercial cannabis laboratory in the United States in 2008, and now has company-owned labs in Berkeley, CA, and Seattle, WA, with licensed labs in Denver, CO and Las Vegas, NV with plans to open a new lab in Albuquerque, NM, and a licensed location in Portland, OR. Steep Hill's core business is testing and analyzing cannabis to ensure compliance with public safety standards. In addition to its core business,

[74] Queensland Health, Forensic and Scientific Services, Archerfield at http://www.health.qld.gov.au/qhcss/qhss/fss/chem-analysis.asp
[75] SC Labs website at http://sclabs.com/about/about-sclabs.html.
[76] PhytaLab website at http://phytalab.com.

Steep Hill is also an innovative R&D Lab that has developed and commercialized two highly-differentiated and proprietary products: the QuantaCann™ and the GenKit for sale or lease to the public.™[77]

Interim Measures

Access to and funding for quality controlled cannabis oils to be imported from legally registered overseas suppliers or through local suppliers if available via the TGA special access scheme.

An amnesty program and interim measures are discussed in more detail below.

Stage 2: Cannabis for Medical Purposes in Queensland

Insert a new part in the *Drugs and Poisons Regulation* pursuant to provisions in Part 4 and Part 4A of the *Health Act* titled 'Cannabis for Medical Purposes,' and adequate provisions thereunder for the regulation and control of cannabis solely for medical purposes within the State of Queensland, with specific provisions for patients, carers, nominated carers, medical practitioners and other key stakeholders as follows:

- *An Office for Cannabis for Medical Purposes in Queensland*

  The establishment of a separate office under the administration of the Minister for Health to oversee the regulation and control of the cultivation, production and manufacture, sale and supply, possession and use of cannabis, cannabis resin, cannabis oils; and manufactured cannabinoids and other cannabis products for sale and supply within the State of Queensland.

- *Independent Advisory Board*

  The establishment of an independent advisory board with a committee comprised of qualified people and patient advocates representing the key stakeholders during the initial stages of reform, and for all matters concerning the ongoing regulation and control of cannabis for medical purposes within the State of Queensland.

- *Medical Cannabis Program*

  The establishment of a 'Medical Cannabis Program' with adequate provisions for the Chief Executive Officer of Health to make regulations to allow for the following:

  - the introduction of a statewide photo identification card system and register for qualifying patients, carers and nominated carers
  - approval to be granted to a qualifying patient, carer or nominated carer to be authorised to cultivate, produce, supply, possess, obtain and use botanical cannabis, cannabis resin and cannabinoids for medical and human therapeutic use, and authorised associated activities
  - approval to be granted to the patients, carers and nominated carers registered under an amnesty to be authorised to continue undertaking the same permitted activities specified under his or her amnesty, as a registered and authorised person under a Medical Cannabis Program
  - approval to be granted to registered medical practitioners to be authorised to treat patients under a cannabis treatment plan
  - approval to be granted to medical cannabis cooperatives registered within Queensland to cultivate, produce and supply cannabis and cannabis oils, and provisions for other services including cannabis dispensaries

[77] Steep Hill website at http://steephill.com/companies.

- specific conditions, monitoring, investigation, offences and enforcement
- research, education, training and support services
- registration fees to assist with the funding of the progam
- any other provisions deemed necessary.

A paper to discuss provisions for the introduction of a medical cannabis program for patients, carers and other stakeholders and other measures has been prepared, and will be released shortly to take into account consultation and feedback from this paper.

Stage 3. Commercial Cultivation and Production of Cannabis for Medical Purposes

The regulation of the commercial production of cannabis under existing provisions should ensure that the safety and quality of cannabis products are maintained at all stages from cultivation and manufacture, through to wholesale supply to approved pharmacies and dispensaries, to the patients who cannot or do not wish to cultivate and produce their own cannabis and cannabis oils

To insert a new part in the *Drugs and Poisons Regulation* pursuant to provisions in Part 4 and Part 4A of the *Health Act* titled 'Commercial Cultivation and Production of Cannabis' with adequate provisions thereunder that will allow for:

- a person to be granted a licence to be authorised to undertake regulated and controlled activities to undertake the commercial cultivation, production and supply of cannabis and cannabis products for wholesale supply to approved licensed dispensaries and pharmacies
- the screening of participants, quality assurance standards, security and monitoring including tracking and inventory control of plants and products, independent laboratory analysis, packaging and labeling requirements, advertising and promotion restrictions and any other measures deemed necessary to prevent theft and to control the risk of diversion
- offences, monitoring, investigation and enforcement
- licence fees to assist with the costs of the system
- any other provisions deemed necessary.

Stage 4. Research and Science

- *Research Trials - Participants of the Amnesty Program*

  Funding for research trials to be conducted into the use of cannabis by patients participating in the amnesty program rather than the Queensland Government participating in trials conducted by the New South Wales Liberal Government that are not set to commence until the middle of 2016. It should be noted that he research trials in New South Wales, will in any case, be experimenting with cannabis products, on participants, that will be classified as unapproved products under the Commonwealth *Therapeutic Goods Act,* as they would not have been evaluated for quality, safety and efficacy by the Therapeutic Goods Administration, and for all intents and purposes is similar to what patients and carers are currently cultivating and producing themselves.

- *Research, Science and Education and Training Centre and State-wide Laboratory Reference Library*

  - Funding for a state of the art cannabis research center to foster research on cannabis, cannabinoids and the endocannabinoid system and research on the cultivation of cannabis and different production methods.
  - Research scholarships for Queensland students.

- Funding for a world class conference centre, and an information and resource service to serve the medical profession, industry and the public with reliable and up to date information regarding the therapeutic uses of cannabis and its chemistry, toxicology and other effects of its constituents that interact with the endocannabinoid system.

- Funding for the development and maintenance of a state wide laboratory reference library or contract with an organisation that represents state testing laboratories, to be responsible for maintaining a reference library that contains a catalogue of methodologies for the analysis of cannabis and cannabis products in the areas of potency, homogeneity, solvents, microbes, pesticides and other contaminants. The reference library would also responsible for addressing proficiency testing and remediating problems with licensed laboratories accessed by the cannabis industry for mandatory testing of cannabis and cannabis products for quality control and product information and labelling purposes.

Further details of stages two, three and four will be released separately to this paper.

Stage One: Amnesty and Interim Measures

Background

At present in Queensland thousands of patients and carers, many with young children are "*out of necessity*" breaking the law[78] and risking criminal prosecution under state criminal laws either by growing their own cannabis or obtaining their cannabis and cannabis oils from the illicit market.[79]

Many carers are also parents caring for children with life threatening or chronic and disabling medical conditions, and who are also living under the threat of the intervention of child safety services, or the Queensland Police Child Protection and Investigation Unit. These parents and carers are risking a maximum penalty of 25 years imprisonment for the serious offence of aggravated supply of a dangerous drug by administering cannabis to a child under the age of 16.[80]

Patients and carers who are unable to cultivate and produce their own cannabis or cannabis oils are also reliant on the illicit market, and are in many cases being exploited and paying exorbitant prices for goods that are unfit for human consumption.

Compassionate Access

Many patients, carers, medical practitioners, politicians and community organisations have voiced their support for the compassionate use of botanical cannabis for medical use where there is clinical justification on the grounds that the standard treatments have either been trialled for appropriate periods of time without sufficient therapeutic benefit, or the standard treatments are not tolerated by the patient or are contraindicated for the patient. Whilst conclusive evidence regarding the safety and effectiveness of botanical cannabis has been limited, due to the restrictions that have been placed on research, there is an abundance of emerging evidence that many patients have benefited from its use for a range of conditions and symptoms.

Patients are already struggling trying to cope with the daily activities and cost of living with a disability and don't need the further burden and stress of living under the threat of criminal prosecution or trying to source their medicine from criminals. This situation is having a detrimental impact not only on the patient's physical and mental health and well-being but on carers and the family unit as a whole.

Patients and carers need an immediate exemption from criminal prosecution, and access to support services, including services where they can have their cannabis tested, especially concentrated oils that are being provided by parents to their children. Parents in particular need a firm commitment and reassurance from the Queensland Government they will not be prosecuted with the intervention of the child services protection unit or their children removed from their care and treatment stopped.

[78] *Drugs Misuse Act 1986* (QLD)
[79] Sections 6, 8, 9, 10 & 11 of the *Drugs Misuse Act.*
[80] ss 6(2)(a).

The Queensland Government can no longer ignore this important public health issue or the health and welfare of thousands of patients, carers and other family members by leaving them in a situation where they have no choice but to break an unjust law and in doing so risk criminal prosecution rather than die or suffer needlessly.

Commitment from the Queensland Government

Patients and carers who are otherwise honest and law abiding citizens who are willing to come under an amnesty program should be able to register as a matter of urgency. Patients and carers will be doing so in good faith and on the grounds that the Queensland Government will provide them with protection from criminal prosecution and the intervention of child protection services. They will be disclosing to their medical practitioners and Queensland Health details of the activities they are currently undertaking or propose to undertake to enable them to access cannabis "out of necessity" and solely for medical purposes.

Patients and carers need a firm commitment from the Queensland Government that they will not be prosecuted by Queensland Police for disclosing details, which currently constitute a criminal offence, and in many cases more than one offence under the *Drugs Misuse Act 1986* or be subjected to the intervention of child services.

Prevention of Diversion and Misuse of Cannabis

We acknowledge that any proposal for an amnesty must strike a balance between a patient's right to choose to use botanical cannabis and the State's responsibility to ensure there are adequate safeguards in place to prevent the diversion of cannabis to the illicit market or access and abuse by minors.[81]

An amnesty will only be available for qualifying individuals under strict guidelines, and on the condition that a patient has in place their own cannabis treatment plan; informed consent has been given to his or her doctor stating that the patient or a carer assumes full responsibility for the use of the cannabis; and has provided an undertaking to Queensland Health by way of a Statutory Declaration that the person will adhere to the strict guidelines and conditions of the amnesty.

To be clear an amnesty is not intended to undermine the role of health or law enforcement agencies or the policing of the illicit cannabis market. The scope of an amnesty is to be constrained by specific conditions and provisions to allow for monitoring, enforcement and investigation powers to ensure participant compliance with the program.

Health and Safety

In the interests of the health and safety of patients we propose that Queensland Health make available the State Analytical Services[82] for the testing of samples of cannabis oils and tinctures for potency, heavy metals, homogeneity, solvents, microbes, mold, pesticides and other contaminants.

Patients and carers of children regard this as an important aspect of medical cannabis treatment and care, especially in the case of children using concentrated cannabis oils to treat life threatening or serious conditions such as cancer and epilepsy, and who may also be receiving treatment with pharmaceutical drugs.

Overall Benefits

The overall net benefits of an amnesty program including patient safety, health and well-being far outweigh any risks for diversion and misuse as these can be mitigated with adequate safeguards. An amnesty will also start to separate the medical use of cannabis from the illicit market and give the Queensland Government the opportunity to receive specific information and feedback about the patients and carers in the community who are using cannabis and the support services they require.

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[81] See for example the Terminally Ill Cannabis Scheme administered New South Wales Health and the Special Access Scheme administered by the Commonwealth Therapeutic Goods Administration.

[82] Queensland Health, Forensic and Scientific Services, Archerfield at http://www.health.qld.gov.au/qhcss/qhss/fss/chem-analysis.asp.

A number of overall benefits have been identified as follows:

Patients and Carers

- afforded protection from criminal prosecution
- not living under constant fear and threat of criminal prosecution or
- not living under constant fear and threat of the child protections services
- many will no longer have to deal with or be exploited by the illicit market
- patients can live with dignity and respect and also be afforded a quality of life
- cannabis can be grown safely and at reasonable standards
- patient access to an affordable and guaranteed supply of cannabis
- patients will be able to trial different strains and forms of cannabis
- cannabis and cannabis oils can be tested for safety and quality
- treatment can be tailored to suit the specific and individual needs of the patient
- patients can have an open relationship with their doctor
- patients will be monitored by their doctor
- access to education and support services, and
- carers can tend to the other needs of the patient and family.

Statistical Information

- age and number of patients using cannabis for medical purposes
- the number of parents or carers supplying cannabis to children
- the conditions and symptoms being treated
- forms, types and amount of cannabis cultivated, produced, supplied, possessed and used
- security and responsible use measures being used by patients and carers
- medical practitioners willing to recommend and monitor cannabis treatment
- number of patients and carers and types of support services required.

Law Enforcement

- police can easily identify individuals who are using cannabis for medical purposes
- the illicit market supply of cannabis will start to be defined from the medical use
- a reduction in profits for criminals exploiting patients in the illicit market
- police resources can be used to combat drug trafficking in far more dangerous drugs
- a reduction in prosecution, legal aid and court time and costs.

Health Services

- patients will be properly monitored by health professionals
- reduction of patient hospitalisation from adverse reactions to pharmaceutical drugs
- reduction in the use of allied services such as ambulance
- resources can be used for disability services.

Amnesty Program

Implementation and Commencement

It is proposed that an amnesty program should be implemented as stage one in any process that allows for changes to be made to the regulations to allow for the medical and human therapeutic use of cannabis.

A person should be granted provisional amnesty on the date the person lodges an application in the approved manner and form, and should receive a notice that the application has been received.

A person is granted amnesty from the date of approval of the application.

A registered person granted or denied amnesty will be notified in the approved manner and form.

Consistency with other Jurisdictions

To promote consistency with the other States this proposal uses similar definitions, terms and legal principles used in the Cannabis for Medical Purposes Bills introduced in the NSW and ACT Parliaments and would also be consistent with the Commonwealth Regulator of Medicinal Cannabis Bill.

This will benefit patients when travelling interstate if reciprocal patient rights were adopted amongst all jurisdictions and will also assist State Health Departments and Law Enforcement Officials with monitoring and law enforcement issues. Ideally all jurisdictions in Australia will eventually implement similar legislation.

Underlying Important Principles

This proposal is based from the outset on these underlying important principles and recognition of these is paramount:

- Recognition that cannabis is indispensible for the relief of pain and suffering and that all adequate measures *must* be made to ensure the lawful availability of cannabis for medical purposes for those patents who may benefit from its use.

- Recognition that one of the most important freedoms patients have when it comes to their health is the fundamental right to preserve their own life, be afforded a quality of life and choose their own medical care and treatment for any condition representing a harm or danger to their health or a diminishment to their quality of life.

- Recognition of society's interest in upholding the concept that all human life is sacred and that it should be preserved if at all possible and rejection of the concept that the state has a right to impose, withhold or dictate an individual's medical care and choice of treatment.

- Recognition that any intrusion into a patient's medical decision-making process through lack of choice, no choice, or an unlawful choice with the fear and the threat of criminal prosecution is a serious deprivation of liberty and a breach of an individual's freedom to make their own choices about their health care and the medication that they have chosen to relieve pain and suffering or to preserve their life or for quality of life purposes.

- Recognition of the doctrine that supports the right to self-determination and patient autonomy and observes the principle of informed consent.

- Recognition that the patient, patient's carer and the patient's medical practitioner are best placed to determine the individuals needs of the patient and to monitor the outcome of health care and treatment.

Recognition that in the ultimate the right of the individual is paramount

Guiding Principles

The Queensland Government commits to international agreements about human and health care rights, which recognise everyone's right to have the highest possible standard of physical and mental health. The recognition of this right is essential for any cannabis for medical purposes legislation to be meaningful.

Any changes to legislation should be guided by the following principles:

- Recognition that cannabis is indispensible for the relief of pain and suffering and adequate measures *must* be made to ensure its availability for medical

purposes.

- Patients with serious medical conditions have a right to receive safe and a high quality and affordable cannabis treatment and a right to access cannabis medical services that address their individual needs and that these services must be provided with professional care, skill and competence.

- Patient's and their carers have a right to be shown respect, dignity and consideration and the cannabis medical services provided must show respect for the patient and carer.

- Patients and carers have the right to be informed about cannabis medical services, treatment, options and costs in a clear and open way and receive services in an open, timely manner with appropriate communication about their cannabis health in a way they can understand.

- Patients have a right to make decisions and choices about their cannabis treatment and cannabis medical services and may join in the decision making process in relation to their treatment and cannabis medical services planning.

- Patients have a right to privacy and confidentiality of their personal information and personal privacy is maintained and proper handling of personal health and other information is assured.

- Patients have a right to comment on or complain about their cannabis treatment and cannabis medical services and to have any concerns addressed and dealt with properly and promptly.

Paramount Principle for Children

The main principle in relation to children who are patients registered under Cannabis for Medical Purposes Scheme is that the safety, wellbeing and best interests of a child are paramount.
Example— If the Chief Executive Officer is making a decision about a child where there is a conflict between the child's safety, wellbeing and best interests, and the interests of an adult caring for the child, the conflict must be resolved in favour of the child's safety, wellbeing and best interests.

Other Principles for Children and Vulnerable Patients

The following are general principles for ensuring the safety, wellbeing and best interests of children and vulnerable patients

(a) A carer or legal guardian has the primary responsibility for the child's or vulnerable person's upbringing, protection and development;

(b) Children and vulnerable people have a right to be protected from harm or risk of harm.

(c) The preferred way of ensuring the safety and wellbeing of patients who are children or vulnerable is through supporting their carer or guardian.

(d) In protecting a child or a vulnerable person, the State should only take action that is warranted in the circumstances.

Key Terms and Definitions

To promote consistency this paper uses the same or similar terms and definitions that are used in the health and criminal legislation and also avoids conflict with provisions in other legislation.

For example the terms used for the activities that can be carried out by patients, carers and nominated carers under an amnesty correspond to the relevant offences in the *Drugs Misuse Act* for which the person requires an exemption from criminal prosecution under that law. For example produce, supply,

possess and possess things have the same meaning as those terms in the *Drugs Misuse Act*.

Life Threatening or Chronic and Disabling Condition or Symptoms

The definition of life threatening or chronic and disabling condition is central to the proposed program because a registered patient may only use cannabis for medical purposes in the relief of pain and suffering from a terminal or life threatening; or chronic and disabling medical condition; or symptoms suffered from a chronic and disabling medical condition, and where the standard treatments have either been trialled for appropriate periods of time without sufficient therapeutic benefit, or the standard treatments are not tolerated by the patient or are contraindicated for the patient.

The definition used is the same as the definition used in the proposal for a regulated medical cannabis program. The definition aims to be inclusive to allow all patients that are using cannabis solely for medical purposes and who are benefiting from its use to be eligible for registration. At the same time the definition does not allow for minor or temporary ailments or the recreational or non-therapeutic use of cannabis.

A person may be eligible to apply for amnesty if they obtain a letter from his or her doctor certifying that they have one of the following:

- a condition from which death is reasonably likely to occur within a matter of months; or from which premature death is reasonably likely to occur in the absence of early treatment, or
- a condition or disease from which permanent or further disability is reasonably likely to occur in the absence of early treatment; or
- a condition or disease that would, if left untreated, be of such a nature as to cause or be likely to cause any loss of a distinct part or organ of the body; or cause or be likely to cause serious disfigurement; or endanger or be likely to endanger life, whether or not treatment is or could have been available; or
- a symptom associated with a chronic and disabling medical condition, or a symptom associated with treatment for a chronic and disabling medical condition certified by the patient's medical practitioner as a symptom suffered by the patient that may be relieved by the use of cannabis.

Examples of life threatening or chronic and disabling medical conditions include but are not limited to:

- Cancer and leukemia
- Epilepsy
- MS
- HIV/AIDS
- Glaucoma
- PTSD
- Crohn's Disease
- Neurodegenerative disorders such as Alzheimer's, Huntington's, and Parkinson's disease.

Examples of symptoms associated with a chronic and disabling medical condition include but are not limited to:

- pain associated with cancer
- neuropathic pain
- seizures
- spasticity
- catabolic wasting or cachexia
- chronic pain
- migraines
- anorexia
- gastro-intestinal pain and disorders.

Chronic and disabling symptoms associated with treatment for a medical condition include but are not limited to:

- treatment resistant nausea and vomiting due to chemotherapy or other forms of drug treatment
- other chronic and disabling symptoms associated with other forms of drug treatment.

A medical condition, symptom associated with a medical condition, or associated with treatment for a medical condition not provided for, may be declared at any time to be a condition or symptom for the purposes of the program.

Permitted Activities

Approval for a person to undertake permitted activities under an amnesty will allow an eligible person to '***lawfully'*** undertake activities, which would otherwise be an offence under the *Drugs Misuse Act* by providing an exemption from criminal prosecution.

For an amnesty to apply, a patient, carer or a nominated carer must register under the amnesty program to carry out the permitted activities that would otherwise be an offence under the *Drugs Misuse Act.*

Permitted activities under an amnesty program are as follows:

- cultivation of no more than 12 cannabis plants, with no more than 6 in flower at any one time
- possession of no more than 1 months supply of dried cannabis and cannabis resin
- possession of no more than 3 months supply of cannabis oil and tincture
- producing no more than 3 months supply of cannabis resin, oil and tincture
- supplying/administering no more than the dosage of cannabis, cannabis resin, cannabis oil or tincture as set out in the patient's cannabis treatment plan

Eligible Person

To be eligible a person must be a Queensland resident and provide evidence of residency in the approved form. The following persons may apply as an eligible person to register under an amnesty:

- Patient
- Carer
- Nominated Carer

Patients

To register a patient must be a Queensland resident, attained the age of 18, and must be using cannabis solely for medical purposes and undertake the following:

- obtain a letter from his or her medical practitioner certifying that he or she has a life threatening or chronic and disabling medical condition, or suffers from chronic and disabling symptoms from a medical condition, and

- prepare an approved cannabis treatment plan and discuss with his or her doctor their cannabis use, and

- provide a written informed consent in the approved form to his or her medical practitioner assuming full responsible for any and all adverse outcomes of his or her treatment with the use of cannabis, and

- provide an undertaking to Queensland Health by way of a Statutory Declaration in the approved form, and

- submit application and supporting documents to Queensland Health in the approved manner and form.

These requirements are discussed in further detail below.

Children

A parent or a primary carer may register a child if the child has a life threatening or chronic and disabling medical condition, suffers from a medical condition or a symptom from a life threatening or chronic and disabling medical condition. Two (2) medical practitioners (one of whom is the child's specialist in the relevant field) must certify that the child has a serious medical condition, and cannabis

would be a beneficial treatment, and one of the child's medical practitioners undertakes to oversee the cannabis treatment, and report on its effectiveness to Queensland Health. Examples of serious conditions may include cancer, childhood leukemia and epilepsy.

Family Law Provisions

Family Law provisions apply under an amnesty program. For a child to be eligible to be registered as a patient, the parent who registers the child must produce a certified copy of the Orders from the Family Court of Australia, or the Federal Circuit Court showing the parent has full responsibility of the health care and treatment of the child.

If the parents have equal or shared responsibility of the health care and treatment of the child both parents must register the child.

To make it clear a parent must not register a child unless they have the legal authority to do so under family law provisions.

Carers

A carer is a person nominated by a patient to be a carer or is the legal guardian of the patient.

In the case of a child a carer may only be the parent or legal guardian of the child, and who is a person who has consistently assumed full responsibility for the housing, health, education and safety of the child.

Each parent may register as a carer if they are both involved with the child's cannabis treatment, and must indicate what activities they each undertake. If the child's parents are separated or reside at separate residences, both parents may be eligible to register as carers for the purpose of administering the cannabis to the child (also see Family Law Provisions).

However, only one parent may register to cultivate the cannabis and produce the cannabis oil for the child. To make it clear both parents must not register to undertake the cultivation of cannabis and production of cannabis oil at separate residences.

Nominated Carers

A registered patient or primary carer may nominate another person to be a nominated carer solely for the purpose of cultivating or producing cannabis and cannabis oils for the patient.

To register as a nominated carer, the person must be a Queensland resident, and must have attained the age of 18 years of age to administer/supply cannabis to a patient.

To register as a nominated carer, for the purpose of cultivating cannabis and or producing cannabis cannabis oils the person must be a Queensland resident, and must have attained the age of 21 years of age (unless exceptional circumstances exist), and must provide an undertaking to Queensland Health in the approved form.

A patient may nominate 3 carers to administer the cannabis.

A carer may nominate two other carers to administer the cannabis.

A patient or carer may only nominate 1 carer to cultivate and produce the cannabis.

A nominated carer may only be a carer for up to 3 patients.

Patient or Carer - Nominated Carer Relationship

Another person nominated by a patient, carer or legal guardian to cultivate and or produce cannabis, cannabis oil for supply to a patient is serving a health need for the patient, and is a person who is merely maintaining a source of cannabis for the patient and does not automatically become the party "who has consistently assumed responsibility for the housing, health, or safety" of that patient.
Specific conditions could be as follows:

- a nominated carer may only receive compensation for actual expenses, including reasonable compensation incurred for actual out-of-pocket expenses incurred relating to the patient-nominated carer relationship and shall not, on the sole basis of that fact, be subjected to prosecution for trafficking or other related offences.

- a nominated carer must keep and maintain receipts for actual expenses incurred.

- a nominated carer must immediately notify the patient, carer and Queensland Health if they are unable to carry out the permitted activities as a nominated carer, or if they have reason to believe they will not be able to carry out the permitted activities as a nominated carer for the full term of the agreement between the parties.

- a nominated carer must immediately notify a patient or carer of any loss, attempted theft or theft of the patient's cannabis, cannabis resin or cannabis oil.

It is the responsibility of the patient or primary carer to ensure that a nominated carer is eligible to register as a nominated carer, and is reliable, responsible and qualified to perform or undertake all of the requisite and necessary activities expected of them including supplying and or administering the cannabis, or cultivating and/or producing cannabis, cannabis resin or oils.

The patient's medical practitioner and Queensland Health are not liable for any non-performance or part performance of the nominated carers contractual responsibilities between a patient or carer and a nominated carer.

The patient's medical practitioner and Queensland Health are not liable for any adverse outcome whatsoever that may arise at any time from the patient/carer - nominated carer relationship.

Conditions of Registration

Patients and carers willing to register for an amnesty must undertake the following:

- obtain a letter from his or her treating medical practitioner, or in the case of a child 2 medical practitioners, one of which must be the child's treating specialist; and

- develop a Cannabis Treatment Plan with his or her medical practitioner; and

- provide written informed consent to his or her medical practitioner assuming full responsibility for all and any adverse outcomes from the use of the cannabis; and

- sign and have witnessed a Statutory Declaration in the approved form

- consent to a National background criminal history check

- submit copies of all documents with an amnesty application if applicable to Queensland Health

- provide three (3) certified copies of approved identification showing his or her Queensland residential address, one of which must be a photo identification,
- pay the registration fee if applicable
- pay analysis fee if applicable.

All documents must be completed, signed and witnessed and in the approved form.

Cannabis Treatment Plan

It is proposed that a cannabis treatment plan for an amnesty could provide for the same or similar details as outlined in the sample Cannabis Treatment Plan in this paper (See Annexure 'A'). It provides for a patient or carer to disclose his or her personal and medical details, how the cannabis is to be used, safe and responsible use, security and safety, and the unlawful activities the person is undertaking or proposes to undertake from which registration for amnesty is required to exempt the person from criminal prosecution under the *Drugs Misuse Act*.

The following is an example of some of the details to be provided:

- name, address, DOB, contact details, and any other relevant details
- name of medical practitioner
- name of specialist medical practitioner in the case of a child
- medical condition/s being treated
- forms and amounts of cannabis proposed to be used
- safe and responsible use measures
- activities carried out or proposed to be carried out
- security and safety measures
- other information for statistical purposes.

Examples of Security and Safety Measures

- cultivation or production of cannabis and cannabis oils is to be carried out in a locked room or fenced area away from children and out of public view
- all cannabis and cannabis oils to be kept out of reach of children
- use of child resistant bottles for cannabis oils with label clearly marking patients name, form of cannabis, warning notice and other details if available
- cannabis oils to be kept in a locked safety box in the fridge or a bar fridge used for the patient's medicines
- grow journal to be kept with details of quantity, strain, nutrients, methods of cultivation of plants, yield and methods of production of oils
- no neighbourhood nuisance such as proximity, smell or noise
- not to be sold to another person
- any theft, attempted theft to be reported immediately to nearest police station and Queensland Health
- no theft of or tampering with electricity.

Examples of Safe and Responsible Use Measures

- for authorised patient use only
- use of vaporiser
- not to be inhaled in the presence of minors
- any adverse effects or reactions to be reported immediately
- no seeking of or use of illicit substances
- no driving of a motor vehicle, boat or operating machinery if affected from use
- not to be used in a public place.

Informed Consent and Access to Unapproved Medicines

In accordance with access to unapproved medicines that have not been evaluated for safety and efficacy by the Therapeutic Goods Administration[83] or Queensland Health,[84] a patient or a carer must sign an informed consent form stating that they will be using his or her own cannabis as set out in the cannabis treatment plan and will assume full responsibility for any and all risks associated with the use of the cannabis. Annexure 'B' includes a sample informed consent form that follows standard informed consent guidelines issued by Queensland Health with minor changes to include the use of botanical cannabis.

The patient must acknowledge that they understand the risks, including the risks that are specific to them, and that his or her doctor has explained to them the following:

- their medical condition/s other relevant procedures or treatment options and their associated risks
- their prognosis and the risks of not having the other treatment
- that cannabis is an unapproved medicine and has not been evaluated for safety and efficacy by the Therapeutic Goods Administration or Queensland Health
- the doctor is only responsible for monitoring the medicinal aspect of the cannabis treatment.
- no guarantee was made to them that the cannabis treatment will improve the condition
- if adverse reactions or events happen during the treatment, they will notify the doctor immediately
- they were able to ask questions and raise concerns with the doctor about their condition, the medicinal aspect of the cannabis treatment, its risks and potential benefits and other treatment options available
- will notify the doctor if they change their mind or cease using cannabis
- will not seek to use any cannabis outside the scope of their Cannabis Treatment Plan approval.

Assessing Applications

Applications should generally be assessed in the order they are received at Queensland Health, and on a case-by-case basis and according to the quality and extent of the information provided with the application.

However priority should be given to applications for registration of children under the age of 18. These applications could be assessed and processed as a matter of urgency by an expert panel of doctors, patient advocates and health and law enforcement representatives.

Patients or carers should also be able to provide any other information they consider important or relevant to the application.

Any amnesty program should allow for an appeal process.

[83] Australian Government Department of Health and Ageing, 'Access to unapproved therapeutic goods via the Special Access Scheme' November 2009 at p 9.
[84] Queensland Health Publication, 'Guide to Informed Decision Making' at pp. 53-54.

Monitoring and Reporting by Medical Practitioners

Medical practitioners who provide letters for their patients would only be required to keep a copy of the informed consent form and the patient's cannabis treatment plan.

A patient should attend for regular check ups to allow his or her doctor to monitor the progress of the medicinal aspect of the treatment. A medical practitioner could provide a report to the Chief Executive of Health within 3 months of commencement of treatment for patients under the age of 18 and at 12 months for other patients if requested.

Statutory Declaration

A patient or carer and a nominated carer must also provide an undertaking to Queensland Health in the approved form and by way of a Statutory Declaration[85] and will adhere to the conditions of an amnesty program, his or her Cannabis Treatment Plan and any other conditions imposed by Queensland Health (See Annexure 'C').

Criminal History

A person must consent in the approved form to allow the Chief Executive of Health, Queensland Health or the Commissioner of Police to undertake a National background criminal history check; or the applicant could provide within 30 days of registration a National Police Certificate based on a search of the person's name against the criminal history records held by police services Australia-wide.

A person is not eligible to register for an amnesty to undertake cultivating or producing cannabis if the person has been charged and convicted with an indictable drug trafficking or other serious drug offence in the past 5 years if commercial gain was proved beyond a reasonable doubt.

However a person may make a written request and submission to the Minister for Health if exceptional circumstances exist. The Minister does not have to approve the application.

However the Minister may approve registration under exceptional circumstances and impose strict conditions and restriction. For example the person may be approved to register to cultivate 1 plant for a qualifying seriously ill patient living in the same household with strict conditions imposed including extra security and monitoring.

Other Conditions

A person registered under an amnesty must adhere to the following guidelines:

- immediately notify Queensland Health if they have been charged with any drug offence under Queensland or Commonwealth legislation
- maintain a journal of activities undertaken and produce his or her documents for presentation to health or law enforcement officials if requested.
- immediately report any loss, attempted theft or theft of cannabis to the nearest police station and Queensland Health. A written copy of the police report is to be provided to Queensland Health within 5 days.
- immediately notify Queensland Health of any change in circumstances
- immediately notify Queensland Health if a patient dies, or is hospitalized or institutionalised or is likely to be hospitalised or institutionalised for any substantial period of time but in any case longer than 4 weeks

Offences

The trafficking, sale or supply of cannabis, cannabis resin or cannabis oils for commercial profit or personal gain is prohibited. If a registered patient, carer or nominated carer does something outside the scope of the amnesty program, the *Drug Misuse Act (QLD)* will apply in full force, and the person dealt

[85] *Oaths Act 1867* (QLD)

with under provisions of that legislation and registration may be cancelled.

Breach of Program

An amnesty should provide for circumstances where the person has a reasonable excuse for performing the activity. For example a patient or carer may need an unregistered carer who is a family member or close family associate to perform an activity such as administering cannabis to a patient or tending to the cannabis plants due to an emergency situation i.e. illness, hospitalisation or a work commitment.

A minor breach of the program may include that a person has inadequate security due to relocating residence however a person will not be in breach if the person takes all steps and measures to mitigate any harm, loss or theft or risk for diversion, and has in place measures to secure the cannabis within a reasonable time frame. If warranted further conditions could be imposed for breaches that may compromise the integrity of the program.

Monitoring, Enforcement and Investigation

A patient, carer or a nominated carer will be required to consent to reasonable inspections or monitoring by Queensland Health or law enforcement officers if requested.

Registration Fee and Analytical Services Charge

It is proposed that a basic annual registration fee of $100 could be imposed to cover costs of the program.

If available, a patient or carer may elect to pay a charge to be able to access the Queensland State Analytical Services if required.

Review

An annual review may be conducted until measures are introduced that will allow for amnesty patients and carers to continue with these activities under corresponding provisions of a state-wide medical cannabis program if they choose, or to be able to access manufactured cannabis products from the commercial sector.

Interim Measures

We propose that as an interim measure the Queensland Government give serious consideration for the approval of funding for the purchase of bulk supplies of quality controlled cannabis oil products to be imported from legally registered overseas suppliers for patients with life threatening conditions particularly children, until a local supply source is lawfully available at affordable prices.

Authorised Prescribers and Funding for the Importation of Bulk Supplies of Cannabis Oils

- to facilitate the process for medical practitioners in Queensland who wish to apply to become authorised cannabis prescribers pursuant to section 19(5) of the *Therapeutic Goods Act 1989*[86] for the purposes of prescribing cannabis oils that can be lawfully imported from overseas suppliers or from local suppliers when available.

- funding for the purchase of bulk supplies of quality controlled cannabis oils from licenced overseas suppliers under the *Therapeutic Goods Act 1989* for authorised cannabis prescribers to prescribe and supply to seriously ill patients with life threatening conditions, in particular patients under the age of 21 years of age until a lawful quality controlled supply is available from local suppliers.

[86] Sections 19(5) and 41HC of the *Therapeutic Goods Act 1989*; and the Therapeutic Goods Administration website at https://www.tga.gov.au/form/authorised-prescribers.

State Approval - Special Access Scheme Applications

- approval to Queensland medical practitioners to prescribe unapproved botancial cannabis and cannabinoid products to patients with life threatening or chronic and disabling medical conditions through the Commonwealth Special Access Scheme (SAS) until a lawful supply is available from local suppliers.[87]

- state approval to Queensland pharamacists or other sponsors applying to supply unapproved botanical cannabis and cannabinoid products, that have to be imported from legal overseas suppliers under an import licence through the Special Access Scheme under Regulation 5 of the *Customs (Prohibited Imports) Regulations* 1956.

- approval to patients and carers to be authorised to lawfully possess and supply unapproved botanical cannabis and cannabinoid products that have been prescribed by Queensland medical practitioners and imported by pharmacists through the Special Access Scheme as above.

Access to Unapproved Medicines - SAS and Authorised Prescribers

In most states the Commonwealth has primary control of the regulatory system with a division of responsibility between the Commonwealth and the States and Territories broadly broken down as:

- Commonwealth regulates and prescribes standards for the importation and exportation and commercial availability of therapeutic substances in Australia and the licensing of drug manufacturers under the *Therapeutic Goods Act 1989.* As mentioned above, Queensland and Western Australia have not adopted the TGA into state law.[88]

- The States regulate the production, cultivation, sale, supply, possession, handling and use of drugs and poisons under state health and criminal legislation. In Queensland the production, cultivation, supply and possession of cannabis comes under the *Drugs Misuse Act 1996.* The scheduling, manufacturing, prescription and sale of therapeutic substances also fall under the *Health Act 1937* and the *Health (Drugs and Poisons) Regulations 1996.*

Legislative Controls

The principal legislation relevant to accessing products that have not been approved in Australia include:

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods (Medical Devices) Regulations 2002*
- *Customs Act 1901*
- *Customs (Prohibited Imports) Regulations 1956* (C(PI) Regulations)
- *Quarantine Act 1908*
- State and Territory laws

Therapeutic Goods Act 1989 (Cth)

Most therapeutic goods for human use that are imported, manufactured in Australia, supplied by a corporation, supplied interstate or to the Commonwealth, or exported are required to undergo an evaluation for quality safety and efficacy and be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

[87] Therapeutic Goods Administration, *'SAS Guidelines'* at https://www.tga.gov.au/sites/default/files/access-sas-guidelines.pdf.
[88] See Regulation 3 of the *Therapeutic Goods Regulations 1990* (Cth) for corresponding state and territory legislation.

Exemptions for Experimental and Special Use of Unapproved Medicines

However in recognition that there are circumstances where patients need access to therapeutic goods that are not on the ARTG, the Therapeutic Goods Administration manages the Special Access Scheme (SAS) and other programs. There are a number of mechanisms for exemptions that allow patients to gain access to products that have not been approved for use in Australia and registered on the ARTG. [89]

Exemptions for experimental and special use may be granted by way of:

- Special Access Scheme (categories A and B)
- Authorised Prescribers
- Personal importation
- Clinical Trials (CTN and CTX schemes)

Any unapproved therapeutic good can potentially be supplied via the SAS with the exception of drugs of abuse where the manufacture, possession, sale or use is prohibited under State or Territory law.

Special Access Scheme (SAS)[90]

Medical practitioners may apply to the Therapeutic Goods Administration to be granted authority to treat a single patient with an unapproved therapeutic good, on a case-by-case basis under a range of circumstances such as:

- early access for terminally ill patients to almost any product including experimental and investigational products (see Category A);
- access to products withdrawn from the Australian market for commercial or other reasons;
- access to products provided initially to patients through a clinical trial while a marketing application is being processed; and
- access to products available overseas but not marketed in Australia.

Patients are grouped into two categories under the scheme:

- Category A patients are defined as persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- Category B patients are all other patients that do not fit the Category A definition.

Sponsors of unapproved products supplied under the SAS are required to notify the Therapeutic Goods Administration any information that has an important bearing on the benefit-risk assessment of the unapproved product, particularly any information that may lead to changes to the usage of the product under the SAS. [91]

Authorised prescribers[92]

Medical practitioners may apply to the Therapeutic Goods Administration[93] to be granted authority to become authorised prescribers to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified patients or classes of patients. Authorised prescribers can prescribe that product for that condition to individual patients in their immediate care without further approval from the Therapeutic Goods Administration.

To be an Authorised Prescriber the medical practitioner must:

- have the training and expertise appropriate for the condition being treated and the proposed

[89] For more information about accessing unapproved medicines see the Therapeutic Goods Administration website at https://www.tga.gov.au/accessing-unapproved-products
[90] Special Access Scheme at https://www.tga.gov.au/form/special-access-scheme.
[91] SAS Guidelines at https://www.tga.gov.au/sites/default/files/access-sas-guidelines.pdf at pp 9 -10
[92] Information about Authorised prescribers can be viewed at the Therapeutic Goods Administration website at https://www.tga.gov.au/form/authorised-prescribers.
[93] Sections 19(5) and 41HC of the *Therapeutic Goods Act 1989.*

use of the product;

- be able to best determine the needs of the patient; and
- monitor the outcome of treatment.

An Authorised Prescriber is allowed to supply the product directly to specified patients under their immediate care and not to other practitioners who prescribe/administer the product. Use of the product under an authorisation must be at all times in line with the conditions specified in the authorisation. Once a medical practitioner becomes an 'Authorised Prescriber' they do not need to notify the Therapeutic Goods Administration when they are prescribing the unapproved product, however they must report to the Therapeutic Goods Administration the number of patients treated on a six monthly basis.[94]

Personal Importation Scheme

Personal importation occurs when:

- an individual either brings a therapeutic good into Australia on their person or arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier; and
- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

Individuals may import medicines without the goods being entered on the ARTG under the following criteria:

- the goods are either for use by the importer or a member of the importer's immediate family, and
- the goods do not contain a substance which is a prohibited import under the C(PI) Regulations, and
- the quantity imported does not exceed three months' supply per importation and the total quantity imported per year does not exceed 15 months' supply at the manufacturer's recommended maximum dosage; or

- importation of the goods is approved under regulation 5 of the C(PI) Regulations or the goods are included in a gazetted class approved for importation under regulation 5; and
- in the case of prescription medicines (ie, Schedules 4 and 8 of the Poisons Standard), the goods are the subject of a prescription issued by a State/Territory registered medical practitioner. Note: medicines carried by a passenger on a plane or ship are an exception to this requirement, however, an import licence is still required in the case of medicines in Schedule 4 of the C(PI) Regulations if the passenger does not have a prescription. [95]

Clinical Trials

Clinical trials of medicines are undertaken to answer questions about their safety and efficacy. The TGA has provisions for two separate schemes under which clinical trials involving unapproved therapeutic goods may be conducted in Australia:

- Clinical Trial Notification Scheme
- Clinical Trial Exemption Scheme

A clinical trial is described by the TGA as an experiment conducted in humans in order to assess the effects, efficacy and/or safety of a medicine, medical device, or a procedure or intervention, and therefore it is necessary that the trial be conducted using appropriate experimental designs to obtain valid data without exposing people to unnecessary risks.

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[94] For further information on authorised prescribers see the Therapeutic Goods Administration website at https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers.

[95] Further information on Personal Importation can be viewed at https://www.tga.gov.au/sites/default/files/access-personal-import-guidelines.pdf.

The primary responsibility for monitoring a clinical trial rests with the sponsor of the unapproved medicine, the institution in which the trial is being conducted and its Human Research and Ethics Committee, and the investigator.

According to the TGA there is no requirement that applications to the TGA to market medicines must contain data from clinical trials conducted in Australia however, the Australian Schemes provide benefits by providing the momentum to research and develop new medicines locally and creating an environment of scientific research, and by providing early access for patients to new therapeutic developments.

An application or notification to conduct a clinical trial involving an unapproved therapeutic good is independent of an application for registration however a notification or application to conduct a clinical trial will be accepted whilst an application for registration of the same product is under review. Similarly, an application for registration will be accepted while a clinical trial for the same product is under review or under way in Australia.

The TGA state that medical practitioners should not use clinical trials primarily as a means for obtaining an unapproved product for a particular patient and advise that they should consult Information on the other mechanisms for access to and supply of unapproved therapeutic goods.[96]

Informed Consent

It is always a condition of the approval to supply an unapproved therapeutic good that the patient or the patient's legal guardian must be in a position to make an informed decision regarding treatment. Informed consent should be in writing unless there are good reasons to the contrary. Informed consent should be freely given to the medical practitioner or sponsor and in line with good medical practice.

The patient should also have an adequate knowledge of his or her condition and its consequences, treatment options, the likelihood of recovery and the long-term prognosis. A patient should be specifically informed of the following:

- that the product is not approved in Australia;
- the possible benefits of treatment and any risks and side effects that are known;
- the possibility of unknown risks and late side effects; and
- any alternative treatments using approved products which are available.[97]

Customs Act 1901[98]

The Customs Act applies to Cannabis, cannabis resin and cannabinoids are listed in Schedule 4 to the *Customs (PI) Regulations*[99] as narcotics, and can only be imported into Australia if a licence, permission, consent or approval to import the goods has been granted as prescribed by the regulations[100] or the *Therapeutic Goods Act 1989*.

The Australian Customs Service will only allow these substances to be imported if the Therapeutic Goods Administration has given written permission for importation. The Therapeutic Goods Administration considers that the use of these substances should be supervised by a medical practitioner and will not issue import permits to individuals. Instead, the Therapeutic Goods Administration requires applications to be made in writing by the individual's medical practitioner under the Special Access Scheme.

A licenced pharmacist may also apply for an import licence or permit to import the products for supply to the patient.[101]

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[96] Therapeutic Goods Administration, 'Access to unapproved therapeutic goods – clinical trials,' October 2004 at p 10
[97] The Australian Government, Department of Health and Ageing Publication, Access to unapproved therapeutic goods via the Special Access Scheme, November 2009 at https://www.tga.gov.au/sites/default/files/access-sas-guidelines.pdf at page 9
[98] *Customs Act 1901* (Cth) at http://www.comlaw.gov.au/Details/C2014C00792.
[99] *Customs (Prohibited Imports) Regulations* 1956 (Cth) at http://www.comlaw.gov.au/Details/F2014C01354
[100] Regulation 50(3)(b)(i)(ii) *of the Therapeutic Goods Regulations 1990 (Cth).*
[101] Therapeutic Goods Administration, *'Application for a licence to import/export narcotic, psychotropic and precursor substances'* at https://www.tga.gov.au/application-licence-importexport-narcotic-psychotropic-and-precursorsubstances#lists.

Responsibilities of the Importer

Individuals using unapproved goods must be aware that in many cases the quality, safety and efficacy of the products may not have been evaluated or may have only undergone minimal testing. They must be prepared to accept any risks associated with the use of the products. If they suffer adverse consequences redress may be difficult to obtain.

It is the responsibility of individuals wishing to arrange importation of unapproved therapeutic goods to ensure they have complied with all relevant Commonwealth and State/or Territory laws.

Goods imported into Australia, whether therapeutic or not, may be subject to import controls administered under the *Quarantine Act 1908* and the *Environment Protection and Biodiversity Conservation Act 1999* if the products are manufactured from animal, plant or human materials.

Promotion of Unapproved Therapeutic Goods

Subsection 22(6) of Chapter 3 (medicines) and Section 41MM of Chapter 4 (medical devices) of the *Therapeutic Goods Act 1989* make it an offence to promote unapproved therapeutic goods. A person must not intentionally or recklessly make a claim, by any means that the person or another person can arrange the supply of unapproved therapeutic goods. An offence carries a financial penalty.[102]

[102] Therapeutic Goods Administration, 'Access to unapproved therapeutic goods - clinical trials,' October 2004 at p 10.

Annexure 'A'

Sample Cannabis Treatment Plan

Queensland Residents Only

Part A

Patient: **DOB:**
Address:
Carer details if applicable: **Relationship:**
Address:
Next of Kin:
Home phone: **Mobile:**
Email:
Primary condition/s:
Primary symptom/s
Medical Practitioner:

Activities requiring amnesty under the *Drugs Misuse Act* 1986 (QLD)

Section 6 - Supply drug - cannabis flower - cannabis oil - cannabis tincture

Section 8 - **Produce/cultivate drug** - cannabis plant/s - cannabis oil - cannabis tincture

Section 9 - **Possess drug** - cannabis seeds - cannabis flower - cannabis resin - cannabis oil - cannabis tincture

Section 10 - **Possess things** - vaporiser - pipe - grinder - fans - lighting - extractor - grow cabinet/tent, pollen press, hash bubble bags, oil/tincture making equipment, solvents, scales, etc

Quantity or amount cultivated/produced	**3 mths**		**6 mths**		**12 mths**
• Cannabis plants in flower	2	4	6	8	12
• Cannabis seedlings	2	4	6	8	12
• Cannabis resin					
• THC/CBD oil/tincture					
• CBD oil					
• Tincture					

Approx. amount possessed / supplied	**Weekly/Monthly/Quarterly**	
• Cannabis seeds	grams	ounces
• Dried botanical cannabis flower	grams	ounces
• Dried botanical cannabis leaf	grams	ounces
• Cannabis resin	grams	
• THC/CBD oil/tincture	mls	
• CBD oil (THC less than 3%)	mls	
• Tincture	mls	

Sample Cannabis Treatment Plan

Queensland Residents Only
Part B

Examples of Security and Safety Measures

- cultivation/production of cannabis, cannabis oils in a padlocked room or secured fenced area away from children and public view
- grow journal to be kept with details of quantity, strain, nutrients, yield, methods of cultivation of plants and/or production of oils
- no neighbourhood nuisance such as proximity, smell or noise
- not to be sold to another person
- dried cannabis to be kept in a locked safe or safety box with key out of reach of children
- cannabis oils to be kept in a locked safety box in fridge or a bar fridge used for the patient's medicines
- no access to key or safety box by non authorised persons including siblings or other minors
- all cannabis, utensils and equipment to be kept out of reach of children
- use of child resistant bottles with label clearly marking patients name, form of cannabis, warning notice and other details if available
- any theft, attempted theft or loss of cannabis to be reported immediately to nearest police station and Queensland Health
- no theft or tampering of electricity

Examples of Responsible Use Measures

- for authorised patient use only
- use of vaporiser or filter screens
- not to be inhaled in the presence of minors
- any adverse effects or reactions will be reported immediately
- no seeking of or use of illicit substances
- no driving a motor vehicle, boat or operating machinery if affected from use
- not to be used in a public place

Patient / Carer Cultivation or Production

Plant Cultivation	Indoor	Outdoors
Cannabis resin produced	Yes	No
Cannabis oil produced	Yes	No
Cannabis tincture produced	Yes	No
Patient / Carer	**Illicit Market**	
Dried cannabis	Yes	No
Cannabis resin	Yes	No
Cannabis oil	Yes	No
Cannabis tincture	Yes	No

Annexure 'B'

Sample Patient Informed Consent

Queensland Residents Only

Informed Consent - Amnesty for Medical Purposes

I acknowledge that my doctor has explained to me:

- my medical condition/s and prognosis
- other relevant procedures and treatment options available and their associated risks and the risks of not having other treatment
- that botanical cannabis is an unapproved medicine and has not been evaluated for safety and efficacy by the Therapeutic Goods Administration or Queensland Health.
- that my doctor is only responsible for monitoring the medicinal aspect of the cannabis treatment and will provide reports to the Chief Executive of Health if requested.

I understand the risks, including the risks that are specific to me / or my child from the use of my own cannabis and am solely responsible for any adverse outcomes; and

- no guarantee has been made to me by my doctor that the cannabis treatment will improve my condition; and
- if any adverse reactions or events happen during my cannabis treatment, I will notify the doctor immediately.

About Your Cannabis Treatment Plan

I was able to ask questions and raise concerns with the doctor about my condition, my proposed cannabis treatment, and its risks and potential benefits, and other treatment options. Any questions and concerns have been discussed and answered to my satisfaction.

I will notify my doctor if I change my mind at any time about my cannabis treatment, including after signing this form but preferably following a discussion with the doctor.

I will not seek to use any cannabis outside the scope of my Cannabis Treatment Plan.

I understand that my medical practitioner may cease to recommend that I use cannabis if I breach the protocol set out in my Cannabis Treatment Plan, amnesty program or any conditions imposed by Queensland Health.

I will be using my own cannabis as set out in my cannabis treatment plan and assume full responsibility for any and all risks associated with the use of cannabis.

Name of Patient / Carer / Legal Guardian .....

Signature ..... **Relationship to patient** .....

Date: ..... **Phone No:** .....

I have explained to the patient / carer / legal guardian all the above points under the Patient Consent section and I am of the opinion that the patient / carer / legal guardian has understood the information.

Name of Doctor/delegate: .....

Designation: .....

Signature: .....

Date: ..... **Phone No:** .....

Annexure 'C'

Oaths Act 1867

Sample Statutory Declaration

QUEENSLAND
TO WIT

I, **[insert full name** of **[insert address]**, in the State of Queensland do solemnly and sincerely declare that

1. I believe that I have justification and excuse at law to use cannabis for medical purposes, and use cannabis out of necessity solely for medical purposes.
2. I wish to come under an amnesty program in the State of Queensland because I am at risk of prosecution under the *Drugs Misuse Act* (QLD).
3. I understand that the cannabis that I am using is an unapproved medicine and has not been evaluated for safety and efficacy by the Therapeutic Goods Administration or Queensland Health.
4. I understand that my medical practitioner is only responsible for monitoring the progress of the medicinal aspect of my cannabis treatment.
5. I have provided written informed consent to my medical practitioner and assume full responsibility for all and any risks associated with the outcome of treatment with my use of cannabis as set out in my Cannabis Treatment Plan.
6. I will attend regular appointments with my medical practitioner who will monitor my status and progress, and provide a report to the Chief Executive Officer, Queensland Health if requested.
7. I will immediately advise my medical practitioner and Queensland Health of any changes in my circumstances.
8. I understand that an amnesty will only apply in the State of Queensland and if travelling overseas or interstate the laws of the Commonwealth and those jurisdictions will apply.
9. I understand that I am responsible for any residential tenancy agreements or similar and that I may be required to obtain permission from my landlord/lessor to carry out some activities.
10. I understand that when a regulatory system is introduced I may be required to consent to registration under a state-wide photo identification card system, and that my registration will be subject to compliance and an annual review.
11. I agree to the use and disclosure of my personal and health information for statistical purposes, and the administration and enforcement of an amnesty program and any future review of the program.
12. I understand that providing false and misleading information may be a criminal offence under the Criminal Code.
13. I understand that if I do any activities outside the scope of an amnesty or my Cannabis Treatment Plan, the *Drugs Misuse Act* 1996 (QLD) will apply and my registration may be cancelled.
14. I believe the particulars I have disclosed in my Cannabis Treatment Plan to be true to the best of my knowledge.
15. I am a resident of Queensland and give an undertaking to Queensland Health that I will adhere to the conditions of an amnesty program, my Cannabis Treatment Plan, and any other conditions that may be imposed by Queensland Health.

And I make this solemn declaration conscientiously believing the same to be true, and by virtue of the provisions of the Oaths Act 1867.

Declarer

Taken and declared before me at **[insert name of town or city and suburb where affidavit signed]** this **[insert date]** day of **[insert month]** 20**[insert year]**, before me.

Justice of the Peace/Commissioner for Declarations

Other Cannabis Reform Measures in Australia

Commonwealth

On 27 November 2014, Australian Greens health spokesperson and Co-Convener of the Parliamentary Group for Drug Policy and Law Reform, Dr Richard Di Natale joined with Senate colleagues from across the political spectrum to introduce the Regulator of Medicinal Cannabis Bill that proposes to make medicinal cannabis available in Australia in under a system similar to the TGA and in accordance with the Convention.[103] The Commonwealth cannot legislate to allow patients or carers to grow and supply their own cannabis, as this needs State approval. If passed the legislation will need a Bill to be introduced in the Queensland Parliament to allow for the commercial cultivation of cannabis in Queensland.

New South Wales

In September 2014 the Baird Government announced the Terminal Illness Cannabis Scheme (TICS). The New South Wales Government is also investing up to $9 million over the next five years to conduct clinical trials to further explore the use of cannabis and/or cannabis products

Clinical Trials

The NSW Ministry of Health will administer clinical trials in the areas of adults with terminal illness, focusing on improving quality of life, and symptoms such as pain, nausea and vomiting; adults with chemotherapy-induced nausea and vomiting, where standard treatment is ineffective. A clinical trial of cannabis derived products will be established for children with severe, drug-resistant epilepsy, through a partnership with the Sydney Children's Hospitals Network.

The clinical trials will be conducted under section 19 of the TGA under provisions for access to unapproved products for experimental use. Applications to conduct the clinical trials will be assessed in two phases: Phase One: Expression of Interest (EIO) and Phase Two: Invitation for full submissions. An independent panel will select those expressions of interest that will progress to Phase Two and to be invited to submit a full submission. Expressions of interest in the adult clinical trial closed on 27 February 2015. Preliminary development work has begun on the EOI's for the pediatric epilepsy trial, which is expected to start enrolling patients in mid 2016. [104]

In April 2015, the Greens, New South Wales lodged three separate applications under the *Government Information (Public Access) Act 2009* (GIPA Act) requesting information about progress and uptake of both the TICS and research trials. Documents released by the New South Wales Police, Ministry of Health and New South Wales Justice show that the implementation of the Baird Government's medical cannabis reforms have been slow and ineffective. Documents released revealed:

1. Only 32 people are registered for the TICS.
2. The NSW police have not once used their discretionary powers to not to charge registered adults
3. Clinical trials-assessment of the Expression of Interest (EOI) applications will not be finalised until the end of June despite the trials being announced in September 2014 and the applications closing in February 2015. [105]

Terminally Ill Cannabis Scheme (TICS) 106

The scheme provides guidelines for police officers in New South Wales to help them determine the appropriate circumstances in which they can use their discretion not to charge adults with terminal

[103] Regulator of Medical Cannabis Bill 2014 - The objects are to establish a Regulator of Medicinal Cannabis to perform the functions of the agency similar to the TGA as referred to in Article 23 of the Convention, as it applies to cannabis because of Article 28 of the Convention; and to provide for a national system, to apply in participating States and Territories for regulating the production and use of medicinal cannabis products, and research, in accordance with the Convention. See http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill

[104] New South Wales Health, Clinical Trials information, at http://www.health.nsw.gov.au/cannabis/pages/default.aspx

[105] For more information see John Kaye, Greens MP at http://www.johnkaye.org.au/tag/medicinal-cannabis/

[106] Further information about TICS can be viewed at the New South Wales Government website at http://www.nsw.gov.au/tics

illness who use cannabis and/or cannabis products to alleviate their symptoms and carers who assist them. The scheme covers the possession of small quantities of cannabis[107] but does not cover the cultivation of the cannabis plant. Many patients and carers still risk prosecution as the scheme only permits possession of small quantities and does not cover cultivation.

To register, New South Wales residents with a terminal illness who are aged 18 years require a medical practitioner who is registered in Australia and involved in their ongoing care to certify that the person has a terminal illness as defined by the scheme. Eligible adults may nominate up to 3 carers who can also register under the scheme. A person may be nominated as the carer for a maximum of 3 adults with a terminal illness. In line with the existing situation regarding the nature of obtaining cannabis, the sourcing of cannabis and cannabis products is a matter for adults with a terminal illness and their carers.

Medical Practitioners are not being asked to prescribe cannabis to adults with a terminal illness or endorse the use of cannabis. The medical practitioner is only certifying that the patient has a terminal illness as defined under the Scheme. For the purpose of the Terminal Illness Cannabis Scheme, the definition of terminal illness is:

> *'terminal illness, in relation to a patient, means an illness which, in reasonable medical judgment will, in the normal course, without the application of extraordinary measures or of treatment unacceptable to the patient, result in the death of the patient.'*

Police may exercise their discretion not to charge adults with a terminal illness and carers if the adult with a terminal illness or carer is registered; the adult or carer possesses no more than the specified maximum amount of cannabis; and the use of or the administration/supply of cannabis by the terminally ill person is at their usual place of residence or any domestic residence.

New South Wales Greens - Cannabis for Medical Purposes Bill

In November 2014, John Kaye, MP for the NSW Greens introduced a private members Bill in the Upper House of the New South Wales Parliament after details emerged that the Baird Governments TICS didn't go far enough. The Drug Legislation Amendment (Cannabis for Medical Purposes) Bill 2014 is an Act to amend the *Poisons and Therapeutic Goods Act 1966 (NSW)* and the *Drug Misuse and Trafficking Act 1985* (NSW) for the introduction of a Statewide registration and photo identification scheme supporting the use of cannabis for medical purposes for residents of New South Wales.[108] Amongst other activities eligible patients and carers can cultivate up to 24 plants annually with 6 in flower at any one time. John Kaye MP recently stated in the media that:

"The Greens will push ahead with our bill introduced into the last parliament to significantly expand the range of conditions for access to medical cannabis. The suffering of tens of thousands of NSW residents with chronic pain, nausea from chemotherapy and other debilitating conditions must no longer be prolonged to satisfy conservative political agendas."

"The number of applications to participate in the Terminal Illness Cannabis Scheme is miniscule compared to the number of people in the community who are currently using the drug illegally to relieve pain and suffering. Almost nothing has been done to promote awareness of the scheme and the exclusion of chronic pain ruled out many otherwise valid participants. Police discretionary powers to not charge terminally ill cannabis users have proved to be all public relations and no benefit. There can be no protection for other valid users and no real gain for the community until there is legislation that makes it clear that relief from pain and suffering is not a crime." [109]

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[107] Cannabis leaf - 15 grams; cannabis oil – 1 gram; cannabis resin 2.5 grams.

[108] More information on the NSW Bill and the cannabis research trials can be viewed at John Kaye's MP website at http://www.johnkaye.org.au/tag/medicinal-cannabis/

[109] James Robertson, *'Marihuana Scheme for Terminally Ill Fails to Attract Patients,'* Sydney Morning Herald, 21 April 2015 at http://www.smh.com.au/nsw/marijuana-scheme-for-terminally-ill-fails-to-attract-patients-20150420-1mp4xc.html

Australian Capital Territory - Cannabis for Medical Purposes Bill

A private members Bill has been introduced in the Australian Capital Territory Parliament by Mr Shane Rattenbury MP who has sponsored, the Drugs of Dependence (Cannabis for Medical Purposes) Amendment Bill 2014.[110] The proposed legislation does not extend regulating the supply of cannabis beyond issuing permits to individuals to grow their own plants also with a 6-plant limit.[111]

Victoria Law Reform Commission

On 19 December 2014, Victorian Attorney-General, the Hon. Martin Pakula MP referred the matter of Medicinal Cannabis to the Victorian Law Reform Commission (VLRC) to report on options for changes to the *Drugs, Poisons and Controlled Substances Act 1981 (VIC)* and associated Regulations to allow people to be treated with medicinal cannabis in exceptional circumstances, and to make recommendations for any consequential amendments which should be made to the *Therapeutic Goods (VIC) Act 2010* and any other relevant legislation.[112]

The inquiry will focus on the interconnecting Commonwealth and Victorian laws that need to be considered when developing options for legalising cannabis for medicinal purpose. The Commission has been asked whether a comprehensive medicinal cannabis scheme should be introduced, in collaboration with the Commonwealth or a more limited scheme introduced by Victoria acting alone. The Commission is undertaking community consultations and has not been asked whether cannabis should be legalised for recreational purposes. The VLRC is to provide their report no later than 31 August 2015.

[110] The exposure draft of the Drugs of Dependence (Cannabis for Medical Purposes) Amendment Bill 2014 can be viewed on the ACT Legislative Assembly website at http://www.legislation.act.gov.au/ed/db_50263/default.asp.
[111] For more details view the ACT Greens website at http://www.actgreens.org.au/medical_cannabis
[112] Victorian Law Reform Commission at http://www.lawreform.vic.gov.au/all-projects/medicinal-cannabis.