Supplementary Submission No 69a

INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

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UNSW AUSTRALIA

Australian Drug Law Reform Initiative

Never Stand Still Law

Inquiry into the use of cannabis for medical purposes
Submission to NSW Parliament by the Australian Drug Law Reform Initiative[1]

Supplementary Submissions

There are several possible ways that medical marijuana could be made available to patients under existing State and Commonwealth laws or with only minor changes to legislation:

1. Have a trial approved by Secretary of Department of Health which would come under existing exemptions in the *Drug Misuse and Trafficking Act 1985* (NSW).
2. The Special Access Scheme under the *Therapeutic Goods Act 1989* (Cth).
3. A trial authorised by the Secretary of Department of Health involving an authorised supplier of medical marijuana.

1. Exemption under NSW Law for possession and Cultivation of Marijuana

Under ss 10 and 24 of the *Drug Misuse and Trafficking Act 1985* (NSW), the Secretary of the Department of Health may grant authorities for people to possess and cultivate drugs for the purpose of scientific research, instruction, analysis or study.

A scientific trial could be established where people diagnosed with certain medical conditions are issued authorities to possess and cultivate a certain amount of marijuana (possibly up to 30g and five plants). These people would have to agree to participate in a trial, the parameters of which could be established by the Department of Health or another organisation experienced in conducting medical trials (**Attachment One**).

This model would be the simplest and quickest way to establish a medical marijuana scheme in NSW. However, the downside is that people would have to purchase their marijuana, plants, or seeds from the black market. Presumably, however, people who currently benefit from medical marijuana are currently doing this.

This model appears to have been recommended by Working Party in 2000 (Recommendations 14 – 17).

[1] The Australian Drug Law Reform Initiative (ADLaRI) is a UNSW law faculty project formed at the end of 2011 with the intent of pursuing a variety of pathways towards drug law reform, education and the achievement of social justice.

2. Special Access Scheme under the *Therapeutic Goods Act 1989* (Cth)

The regulation of Therapeutic Goods under Commonwealth and State law is very complex and this is not intended to be a comprehensive explanation of the regulatory system. However, some sections of the legislation that the Committee may consider investigating further are noted.

Under reg 12A of the *Therapeutic Goods Regulations 1990* (Cth) ("TGA") people can apply to use unapproved medicines if death is reasonably likely within a matter of months or premature death is reasonably likely to occur in the absence of treatment **(Attachment Two)**.

However, access to Schedule 9 drugs is forbidden even for these people, and cannabis is a Schedule 9 drug on the *Poisons Standard 2012*.

But Schedule 9 does have a medical and scientific research exemption (**Attachment Three**). It may depend whether Reg 12A picks up this exemption (and therefore allows trials of marijuana) or if Reg 12A simply bans all substances in Schedule 9.

Section 31 of the *Poisons and Therapeutic Goods Act 1966* (NSW) states that the regulations can modify the Commonwealth TGA. Therefore, NSW may be able to alter its regulations to allow medical marijuana to be part of the special access scheme. **(Attachment Four)**.

The Explanatory Memorandum to the *Poisons Standard 2012* states that "The Schedules contained in the Poisons Standard are referred to under State and Territory legislation for regulatory purposes, which enables restrictions to be placed on the supply of scheduled substances to the public". This suggests that perhaps State and Territory legislation can be modified to allow the supply of Schedule 9 drugs.

It also appears that criminal prosecution by Commonwealth authorities may only happen in certain circumstances: s 5A TGA **(Attachment Five)**.

Under s 6AAA of the TGA, the Commonwealth consents to a State law that can impose a function or power on a Commonwealth officer or authority. **(Attachment Six)**.

Under s 6AAE of the TGA, a State law can confer power on a Commonwealth officer to include a good in the register. **(Attachment Seven)**.

Under s 8 of the *Drugs Misuse and Trafficking Act 1985*, nothing is unlawful if it is authorised under the *Poisons and Therapeutic Goods Act 1966*.

It appears that States do have some power under the TGA to modify their own regulations and even, in some cases, to impose functions or powers on Commonwealth officers. Discussion with Commonwealth Ministers and agencies may be required for further understanding of these powers and how the Commonwealth would react to NSW modifying its regulations to allow marijuana into the Special Access Scheme.

It appears that the representative from the Criminal Law Review Division of the Attorney-General's Department who appeared last week undertook to provide a more detailed analysis of the regulatory system around therapeutic goods. The information contained in this document is simply to assist the committee to consider possible options that may or may not be contained in the CLRD analysis.

3. A trial authorised by the Secretary of Department of Health involving an authorised supplier of medical marijuana.

Under s 25 of the *Drug Misuse and Trafficking Act 1985*, the Secretary of the Department of Health can authorise people to supply prohibited drugs, such as marijuana, for the purpose of scientific research, instruction, analysis or study.

In last week's hearing, the representative of NSW Police stated that his unit often confiscates large numbers of marijuana plants without prosecuting anyone. Presumably these plants are destroyed relatively quickly once it is determined that no prosecution will continue.

The Department of Health could possibly authorise the Police to give some of these plants (or just the seeds) of these plants to an authorised supplier who could grow marijuana plants and supply cannabis to people participating in a trial who have also been authorised by the Department of Health to possess cannabis.

The Department of Health may have to apply to the Commonwealth for permission to trial marijuana for medical purposes. Of interest, under s 9 of the TGA the Commonwealth Minister can make arrangements with the State Ministers for the evaluation of therapeutic goods. **(Attachment Eight)**.

It might also be relevant that the Objects Clause of the TGA provides that the Commonwealth legislation does not apply to the exclusion of a State law if that State law can act concurrently with the Commonwealth law **(Attachment Nine)**. Therefore, it may be possible to ask the Commonwealth Minister whether they consider such a trial to conflict with State law.

It was recommended by the Working Party in 2000 that a similar model (involving the licensed supply of cannabis) be considered by the Government (Recommendation 10).

Attachment One

Appendix 1

Appendix 1. Sample NSP authorisation card

Needle and Syringe Program AUTHORISED PERSON Name: ..... Signature:..... Agency:..... Expiry date:	PHOTO

The bearer of this card whose name and signature appears on the front is authorised by the Director-General, NSW Department of Health, or his/her delegate under Clause 4 of the *Drug Misuse and Trafficking Regulation 2000* to participate in an approved Needle and Syringe Program. Subject to clause 5 and 6 of that Regulation, the authorised person is exempt from the provisions of sections 11, 19 and 20 of the *Drug Misuse and Trafficking Act (1985)* for the purpose of enabling participation in an approved Needle and Syringe Program.

Attachment Two

THERAPEUTIC GOODS REGULATIONS 1990 - REG 12A

Unapproved medicines and biological -- exemption in life-threatening cases

(1) For the purposes of subsection 18 (1) of the Act, all medicines, other than medicines of a class or kind listed in the 9th Schedule to the Poisons Standard, as in force from time to time, are exempted, subject to subregulation (2), from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F).

(1A) For subsection 32CA (2) of the Act, all biologicals are exempt, subject to subregulation (2), from the operation of Division 4 of Part 3-2A of the Act.

(2) The exemption of a medicine or biological is subject to the following conditions:

(a) the medicine or biological is to be given to a person who satisfies the following criteria:

(i) the person is a Category A patient (as defined in subregulation (5)); and

(ii) the person, or the guardian of the person, has given informed consent (as defined in subregulation (5)) to the medicine or biological being given to the person; and

(iii) the medical practitioner by whom, or at whose direction, the medicine or biological is to be given to the person has signed a statement in relation to the person in the form approved by the Secretary for the purposes of this paragraph; and

(b) the medicine or biological is dispensed on the prescription of a medical practitioner who has prescribed the medicine or biological in accordance with good medical practice.

(3) A person who signs a statement referred to in subparagraph (2) (a) (iii) must send a copy of the statement to the Secretary within 4 weeks of signing it.

Penalty: 10 penalty units.

(3A) An offence under subregulation (3) is an offence of strict liability.

Note For ***strict liability*** , see section 6.1 of the *Criminal Code* .

(4) This regulation does not affect the operation of regulation 12.

(5) In this regulation:

"Category A patient" means a person who is 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.

"informed consent" , in relation to treatment or proposed treatment, means consent freely given by a person on the basis of information concerning the potential risks and benefits of the treatment that was sufficient information to allow the person to make an informed decision whether to consent to the treatment.

Attachment Three

CLASSIFICATION

Poisons are classified according to the Schedules in which they are included. The following is a general description of the Schedules. For the legal definitions, however, it is necessary to check with each relevant State or Territory authority.

Schedule 1. This Schedule is intentionally blank.

Schedule 2. **Pharmacy Medicine** – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.

Schedule 3. **Pharmacist Only Medicine** – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.

Schedule 4. **Prescription Only Medicine,** or **Prescription Animal Remedy** – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

Schedule 5. **Caution** – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

Schedule 6. **Poison** – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

Schedule 7. **Dangerous Poison** – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

Schedule 8. **Controlled Drug** – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Schedule 9. **Prohibited Substance** – Substances which 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.

Attachment Four

POISONS AND THERAPEUTIC GOODS ACT 1966 - SECT 31

Application of Commonwealth therapeutic goods laws to New South Wales

31 Application of Commonwealth therapeutic goods laws to New South Wales
(1) The Commonwealth therapeutic goods laws, as in force for the time being and as modified by or under this Part, apply as a law of New South Wales.
(2) Those Commonwealth therapeutic goods laws so apply as if they extended to:
(a) things done or omitted to be done by persons who are not corporations, and
(b) things done or omitted to be done in the course of trade or commerce within the limits of New South Wales.
(3) The regulations under this Act may modify the Commonwealth therapeutic goods laws for the purposes of this section.

Attachment Five

THERAPEUTIC GOODS ACT 1989 - SECT 5A

Application of the Criminal Code--extended geographical jurisdiction

Section 15.2 of the *Criminal Code* (extended geographical jurisdiction--category B) applies to offences against subsections 21A(1), (2) and (4) and sections 22A, 41FE, 42E and 42T.

Attachment Six

THERAPEUTIC GOODS ACT 1989 - SECT 6AAA

Commonwealth consent to conferral of functions etc. on its officers and authorities by corresponding State laws

(1) A corresponding State law may confer functions or powers, or impose duties, on:

(a) a Commonwealth officer; or

(b) a Commonwealth authority.

(2) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:

(a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on Commonwealth officers or Commonwealth authorities; or

(b) the authorisation would otherwise exceed the legislative power of the Commonwealth.

(3) Subsection (1) does not extend to a function, power or duty of a kind specified in regulations made for the purposes of this subsection.

(4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on a Commonwealth officer or Commonwealth authority to the extent to which that law:

(a) is consistent with subsections (1) to (3); and

(b) is capable of operating concurrently with this Act.

Attachment Seven

THERAPEUTIC GOODS ACT 1989 - SECT 6AAE

Consequences of State law conferring duty, function or power on Commonwealth officer or Commonwealth authority

(1) If a corresponding State law confers on a Commonwealth officer or Commonwealth authority:

(a) the function of including goods in the Register; or

(b) the power to include goods in the Register;

the officer or authority may include the goods in the Register in accordance with the corresponding State law.

(2) If a corresponding State law authorises or requires a Commonwealth officer or Commonwealth authority to cancel the inclusion of goods in the Register, the officer or authority may cancel the inclusion of the goods in the Register in accordance with the corresponding State law.

(3) The inclusion of goods in the Register under subsection (1) does not subject any person to any liability whatever under this Act, except a liability under Part 6-1.

(4) A Commonwealth officer or Commonwealth authority may make any notations in the Register that the officer or authority considers necessary to identify entries that relate to goods included in the Register under subsection (1).

(5) Goods may be included in the Register under subsection (1) even though the same goods have already been included in the Register under another provision of this Act.

(6) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods:

(a) in the part of the Register for goods known as registered goods; or

(b) in the part of the Register for goods known as listed goods; or

(ba) in the part of the Register for biologicals included under Part 3-2A; or

(c) in the part of the Register for medical devices included under Chapter 4.

Attachment Eight

THERAPEUTIC GOODS ACT 1989 - SECT 9

Arrangements with States etc.

(1) The Minister may make arrangements with the appropriate Minister of a State, of the Australian Capital Territory or of the Northern Territory for the carrying out by that State or Territory, on behalf of the Commonwealth, of:

(a) the evaluation of therapeutic goods for registration; or

(aa) the evaluation of a biological, other than a Class 1 biological, for inclusion in the Register under Part 3-2A; or

(b) the inspection of manufacturers of therapeutic goods; or

(c) other functions under this Act or the regulations.

(2) An arrangement under this section may provide for the payment to a State or Territory of amounts in respect of the performance of functions under the arrangement.

Attachment Nine

THERAPEUTIC GOODS ACT 1989 - SECT 4

Objects of Act

(1) The objects of this Act are to do the following, so far as the Constitution permits:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia, whether produced in Australia or elsewhere; or

(ii) exported from Australia;

(b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

(1A) The reference in paragraph (1)(a) to the efficacy of therapeutic goods is a reference, if the goods are medical devices, to the performance of the devices as the manufacturer intended.

(2) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.