

**Access to cannabis for  
medical and scientific purposes**

**Regulation Impact Statement**

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## Introduction

There has been increasing public discussion about the medical and scientific use of cannabis, with several states and territories exploring options to provide access to cannabis for specified conditions through clinical trials or other authorised mechanisms. The Australian Government has made a commitment to work collaboratively with the States and Territories to share knowledge and information on issues relating to the appropriate use of therapeutic products derived from cannabis, and also to consider health and law enforcement concerns in the context of the Commonwealth's authority and obligations for the control of the cannabis plant when used for medical or scientific purposes in Australia.

On 17 October 2015, the Commonwealth announced its intention to make amendments to the *Narcotic Drugs Act 1967* to enable the cultivation of cannabis for medicinal and scientific purposes in a way that is compliant with Australia's international obligations while facilitating the production of medicinal cannabis products for clinical trials and for specified patients under clinical care in accordance with the *Therapeutic Goods Act 1989*.

This announcement was in response to a cross party bill, the Regulator of Medicinal Cannabis Bill 2014, which was introduced into Parliament in November 2014. The Bill was referred to the Senate Legal and Constitutional Affairs Legislation Committee in February 2015 and tabled its report in August 2015. The amendments that the Narcotic Drugs Amendment Bill will introduce, will address the structural issues that the Senate Committee identified in the report.

While the Department had commenced developing a Regulation Impact Statement for the proposed Bill, it was not possible to assess the full implications of the regulatory changes until the detail of the regulatory framework was developed.

This Regulation Impact Statement (RIS) outlines the Australian Government's options for facilitating access to medicinal cannabis products for medical and scientific purposes.

The term 'medicinal cannabis' has been used interchangeably to mean either: the smoking or eating of raw, herbal cannabis for the notional relief of symptoms; or the use of pharmaceutical products derived from the active compounds of cannabis. The distinction between regulated pharmaceutical products and the use of raw cannabis herb for recreational or therapeutic purposes in this context is that regulated products have been tested for quality, safety and efficacy prior to being registered for consumer use.

## Background

*Cannabis sativa* (cannabis) is a narcotic drug that is tightly controlled in Australia. The cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis derived products are regulated by a number of Commonwealth laws. These laws include the:

1. *Criminal Code 1995*, which makes it illegal to traffic, import, export, manufacture, cultivate or possess cannabis in any form;
2. *Narcotic Drugs Act 1967*, which addresses the manufacture of narcotic substances (including cannabis);
3. *Customs Act 1901*, which addresses the import and export of narcotic substances, including a regime under the *Customs (Prohibited Imports) Regulations 1956* that allows for the importation of cannabis for medical and scientific purposes;
4. *Therapeutic Goods Act 1989*, which addresses the regulation of authorised medicines and medical products; and
5. *Quarantine Act 1908*, which provides the legislative basis for human, plant and animal quarantine activities in Australia.

In addition, various Commonwealth, State and Territory laws provide penalties for possessing, using, making, selling, or driving under the influence of cannabis. There are also laws that prevent the sale and possession of bongs and other smoking equipment in some States and Territories (**Attachment A**).

Australia is a party to international agreements that aim to restrict production, manufacture, export, import, distribution, trade, and possession of narcotic drugs (including cannabis) exclusively to medical and scientific purposes.

The Commonwealth has responsibility for ensuring that any Commonwealth, State or Territory scheme for the cultivation of cannabis for medicinal purposes is consistent with Australia's international obligations under the following three international drug control conventions:

1. the *Single Convention on Narcotic Drugs (1961)*, which specifies the obligations of signatory states in relation to narcotic drugs listed in schedules annexed to the Convention;
2. the *Convention on Psychotropic Substances (1971)*, which aims to limit the use of psychotropic substances to medical and scientific purposes and also to ensure their availability for those purposes; and
3. the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)*, which aims to promote cooperation between parties to address various aspects of illicit traffic in narcotic drugs and psychotropic substances.

Under the United Nations *Single Convention on Narcotic Drugs, 1961* (Single Convention) as amended by its 1972 amending Protocol, Australia, through the Commonwealth Government, has an obligation to carefully control, supervise and report on various stages of cannabis cultivation, production and manufacture. The purpose of the Single Convention is to establish a framework to both prevent abuse and diversion of controlled narcotics and to facilitate the availability of such drugs for medical purposes. The enabling legislation for these obligations is the Narcotic Drugs Act, which is administered by the Health Portfolio, in concert with the Attorney-General's Department.

Article 5 of the Single Convention confers certain functions on the International Narcotics Control Board (INCB) (**Attachment B**), which includes publication of an annual report that provides a comprehensive account of the global drug situation, analyses trends in drug abuse and drug trafficking and suggests necessary remedial action. In addition, the INCB also publishes technical reports on narcotic drugs and psychotropic substances that provide details on estimates of the annual legitimate requirements of each country, as well as data on the licit production, manufacture, trade and consumption of drugs worldwide.

As a signatory to the Single Convention, Australia is obliged to regularly provide information to the INCB to allow it to carry out these functions. Failure to meet those international obligations contains certain risks, including potential damage to Australia's international reputation for its progressive, balanced and comprehensive approach to dealing with the problems posed by the use and misuse of drugs in the community.

The INCB also requires annual estimates of the areas harvested, amounts produced, amount of raw material and refined products in stock, amounts required for importation in the current and next calendar year, estimates for cultivating in the next calendar year, relevant trends in use for medical purposes, estimates of the areas to be used for cultivation in the next year and quantities obtained by the manufacturers. All of these requirements are exemplified in the 2015 reporting requirements for the INCB at **Attachment C**.

Australia, as a Member State of the Commission on Narcotic Drugs (CND), would be required to report these estimates, in relation to cannabis, to the INCB annually or more frequently. In order to meet these requirements, the Australian Government Department of Health would require manufacturers to regularly report these estimates to the Department.

The Commonwealth currently has laws to regulate the import, export and manufacture of cannabinoids and cannabis raw material, but these do not allow the lawful cultivation in Australia of cannabis plants for medicinal purposes.

#### *Cultivation of cannabis*

Presently, the Commonwealth is unable to grant licences for the production of locally cultivated and produced cannabis for medical use and remain compliant with the obligations in the Single Convention or the Narcotic Drugs Act.

Currently, States and Territories can authorise cultivation of cannabis for horticulture and industrial purposes as allowed under the Single Convention. However, if a State or Territory were to authorise cultivation for medicinal purposes, this would enliven the Commonwealth's obligations under Article 23 of the Single Convention. This would require the Commonwealth to establish an authority to regulate the cultivation of cannabis for medicinal and scientific purposes.

There are already mechanisms in place to enable access to medicinal cannabis products through the *Therapeutic Goods Act 1989*, which allows for access under clinical trials and access under the Special Access and Authorised Prescriber Schemes for individual patients. The difficulty and cost of obtaining medicinal cannabis products from international suppliers, however, creates an access issue for the conduct of clinical trials and for people who may potentially benefit from using cannabis for medicinal purposes. Enabling the potential to cultivate cannabis for medicinal purposes locally will mean that there

is potentially a level of supply that meets the demands for clinical trials or other access options. The inability to readily access supplies also creates an environment where black markets for medicinal purposes are forming, thus posing potential dangers to the consumer as products are not tested or monitored for quality or safety.

There are already provisions in the Narcotic Drugs Act through which manufacturing of a narcotic drug can be licensed (as have been used for the processing of poppy straw for many years). The cultivation of cannabis is not currently controlled under the Act. Refining, extraction or other processes (e.g. making extracts, tinctures, cannabis oil) from cannabis (including industrial hemp) is subject to the manufacturing controls set out in the Narcotic Drugs Act.

#### *Consumer access to cannabis*

In relation to consumer access, there are a number of pathways for lawful access to cannabis for medical use through the Therapeutic Goods Act. These are not under review as part of this proposal. This information is provided by way of background. Assuming there is a suitable source of cannabinoids available; pathways for lawful access to cannabinoids for medicinal use are:

1. medicines registered on the Australian Register of Therapeutic Goods (ARTG);
2. clinical trials (such as the trials being conducted in New South Wales and Victoria); and
3. the Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).

Access to cannabis for medicinal purposes through the first pathway, such as occurred for Sativex, requires a robust dossier of clinical trial and other data and is commonly submitted after some years of significant commercial investment. Access through the second pathway is a matter of either seeking the approval of a human research ethics committee and notifying the Therapeutic Goods Administration (TGA) or seeking approval of both an ethics committee and the TGA, depending on the levels of risk associated with the clinical trial proposal. The third pathway has always been a potential mechanism and it has been used to prescribe imported product. Access to products under SAS, however, is undertaken by application to the TGA on an individual basis and requires the patients to source their own products from international suppliers, which can be cumbersome and costly exercise. Under the Authorised Prescriber Scheme, the TGA approves a medical practitioner to prescribe defined but unregistered medications to patients with defined conditions. This has not been used for a medicinal cannabis product, to date.

Some cannabis product has been supplied through SAS Category B over the last 10 years. However, global sources of appropriate medicinal product are limited. As a result, there are widespread reports of patients (and parents of patients that are children) turning to illicit sources of product touted as 'medicinal', produced without any controls on its manufacture ensuring safety and quality. Such patients/parents see that it is necessary to engage in this criminal activity and are taking risks with the quality of the medicines they are acquiring and in their association with criminal activity.

Cannabis and cannabis products for medicinal purposes have been available in some countries for over a decade. This includes overseas jurisdictions such as Canada, 21 states of the United States, Israel and the Netherlands.

Access to internationally sourced cannabis for medical and scientific purposes is difficult and expensive. No current international model features market authorisation of raw or minimally processed herbal

cannabis from any national medicines regulator. In some jurisdictions people are able to access raw herbal cannabis for smoking, either grown by them or grown commercially, on compassionate grounds, usually through a permission scheme on recommendation by a medical clinician. This approach has some risk as raw herbal cannabis can be of varying strength and composition making dosing inaccurate, along with the respiratory risks associated with inhaling smoke from raw dried plant matter.

## **Section 1: The problem to be addressed**

There are community expectations that there should be a licit source of cannabis for medicinal use. The fact that there is illicit cannabis being used for medicinal purposes is concerning as there are no controls on quality or strength nor is there a prescribing service that is professionally based, nor any system for tracking clinical outcomes, including adverse events. This could expose the community to potentially dangerous substances and outcomes.

There is a risk that Commonwealth legislation could be inconsistent with that of the States and/or Territories. In such a case, the Commonwealth is potentially in breach of its international obligations under the Single Convention with at least one State unilaterally moving to permit cultivation of cannabis for medicinal purposes, either to supply clinical trials or to supply some form of access scheme.

There is also increased attention to reports that suggest cannabis is beneficial in the treatment and symptomatic relief for some health conditions. Subject to appropriate safeguards, failure to enable supply of cannabis for medicinal purposes, as well as further scientific study into this treatment option, could deny patients access to new, safe and effective medicines and treatments.

## **Section 2: Objectives**

The use of any medication should be, as much as possible, based on the scientific evidence of its quality, safety and efficacy. However, there are some circumstances where use is not based on comprehensive data supporting efficacy, but rather the professional judgement of a medical practitioner that it is appropriate to try an unregistered (and, as such, unassessed) therapeutic good. The Australian Government is committed to ensuring any therapeutic product, including cannabis for medicinal purpose, is not only a safe treatment for public use, but also meets our strict international obligations safeguarding its production, manufacture and distribution for medical purposes only.

## **Section 3: Options to address the problem**

Only two options have been considered as part of this proposal. This is because the options are, to a large extent, directed by the requirements of the Single Convention, which means the Commonwealth options are limited. Accordingly, the only feasible options relate to whether the Commonwealth will enable cultivation in a way that is consistent with Australia's international obligations and which ensures secure supply with minimal risk of diversion.

**Option 1** - Maintaining the status quo and taking no regulatory action to enable cultivation.

**Option 2** - Establishment of a Commonwealth licensing scheme to facilitate the right to cultivate cannabis for medicinal purposes

Option 2 would require amendments to the Narcotic Drugs Act to enable Australia to cultivate, produce and manufacture cannabis and cannabis products to facilitate access to regulated medicinal products and related scientific research in a way that fulfils Australia's international obligations.

## Section 4: Impact of the options

### Option 1– Status quo

At the Federal level, the status quo means that there would be no legislation to enable lawful cultivation of cannabis for medicinal purposes. Access would still be possible through pathways under the Therapeutic Goods Act, but for imported products, supply of which appears to be insufficient to meet demand.

The status quo will continue to severely limit options for patient access to cannabis for medicinal purposes through the pathways available under the Therapeutic Goods Act and for advancing the scientific understanding of this herbal product through rigorous clinical trials.

Without Commonwealth regulation consistent with Australia's international obligations, States and Territories moving ahead with cultivation will affect Australia's ability to present itself as compliant with the Single Convention. This could have adverse reputational implications for Australia's licit poppy industry with medium term risks to Australia's approved status as a major supplier of poppy straw in a timely controlled manner.

Option 1 will also potentially result in inconsistency in the legislation surrounding the cultivation and production of cannabis for medicinal purposes between the States and the Commonwealth.

Various pieces of legislation exist to ensure the Australian public is protected from false therapeutic claims while continuing to access safe and effective medicines. Maintaining the status quo would reduce the Commonwealth's ability to continue to ensure the public is protected from these claims. If not closely monitored, this may lead to increased use of or public misperceptions about the safety and efficacy of herbal cannabis.

Under this option, the existing risks associated with accessing medicinal cannabis from the illicit drug market remain.

### **Option 2– Establishment of a Commonwealth licensing scheme to facilitate the right to cultivate cannabis for medicinal purposes in a way that is compliant with Australia's international obligations.**

Under Option 2, Australia would have a regulatory system that supports the end to end process of supplying medicinal cannabis products consistent with its international obligations and that works congruently with State and Territory legislation.

It is not possible to quantify the benefits of this option but the qualitative benefits involve facilitating state based regulatory decisions to allow Australia to develop safe, legal and sustainable local supply of cannabis for medicinal or scientific purposes. In turn, this would support greater local opportunities to

research, develop, manufacture and supply medicinal cannabis-based products. Australians would have increased access to high quality medicinal cannabis products. Researchers would be better able to undertake scientific research into the benefits (or otherwise) of medicinal cannabis products.

This option would avoid the prospect that individual jurisdictions will take different approaches to authorising cannabis and cannabis-derived products for medical and scientific use. While some jurisdictions have already commenced action to do this, others are yet to do so.

This option will not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term, but will facilitate further clinical trials that may support such a registration in the future. Cannabis material cultivated and manufactured in Australia would be able to be used to conduct clinical trials and develop therapeutic products to be used in accordance with the Therapeutic Goods Act.

The granting of licences would be dependent on market forces, as well as compliance with licensing conditions as described in the proposed amendments and associated regulations. In addition, facilitating cultivation in Australia of legal cannabis crops for medicinal use under strict local controls strikes the right balance between patient access, community protection and our international obligations.

From a law enforcement perspective, there are a number of issues requiring consideration by the States and Territories when exploring options for access to cannabis for medicinal purposes, including:

- ensuring secure possession and use among identified patients and carers;
- preventing crime groups or individuals influencing the production, supply, transportation and administration of cannabis, for its approved use;
- child safety and welfare requirements;
- road safety enforcement relating to driving under the influence of cannabis; and
- crime associated with increased diversion of controlled drugs to unauthorised use or misuse.

These issues are critical for the robust and credible operation of a licensing scheme but are not relevant for the proposals considered by the RIS.

The proposed regulatory requirements, including an identified and described line-of-sight to prescribers and patient groups, as allowed for under the Therapeutic Goods Act, as well as significant security requirements mean that it is not expected there will be a large industry in the short to medium term.

#### *Compliance costs*

While the cost impact is difficult to estimate in the absence of a current scheme, costs associated with the Commonwealth scheme may include application fees, enforcement and monitoring charges, costs linked to the scheme's obligations (such as record keeping and reporting) and costs associated with complying with the conditions of the licences, including fit and proper person documentation requirements.

The option could potentially incur start-up and ongoing costs to industry. Industry would also need to be educated on the new regulatory requirements and would potentially need to make changes to existing practices to accommodate them. Industry would also have to commit to monitoring, compliance and administrative costs incurred to demonstrate ongoing compliance with the regulation, including record keeping and reporting costs. Costs may include application fees, the time taken to pay licence fees,

purchase and maintenance of plant and equipment to meet regulatory requirements, fees paid to training providers, provision of information to third parties (such as background checks on staff) and operational costs.

There are several options for facilitating access to cannabis/cannabis products for medicinal and scientific purposes in Australia; however, any option that entailed cultivation of cannabis for non-industrial/horticultural purposes in Australia would trigger specific obligations under the Single Convention. This would involve a Commonwealth authority furnishing estimates on production levels to the International Narcotics Control Board (INCB)<sup>1</sup>, designating cropping areas, licensing cultivators, as well as maintaining exclusive right to import and export, wholesale trading, and maintaining stocks other than those held by manufacturers through a Single Agency (Single Convention Articles 23 and 28 - refer **Attachment D**).

The following costs have been excluded from the calculation:

Opportunity costs (unless they relate to a delay) – the quantification of opportunity costs is difficult due to the complexity in accurately predicting what a business would do as an alternative to this option;

1. Business-as-usual costs – the costings have only measured regulatory burden over and above what a normally efficient business would undertake in the absence of regulation;
2. The costs of non-compliance – this includes costs such as fines for failing to comply with a licence condition and legal fees; and
3. Indirect costs – these are costs that arise indirectly from the impacts of regulatory changes, including changes to market structure and competition impacts.
4. It is estimated that the Agency will incur costs of around \$43,000 per year, estimated over a 10 year period.

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<sup>1</sup> The INCB is the United Nations body charged with overseeing the global licit narcotics industry. It is established under the Single Convention and, among other things, approves estimates on consumption and production that controls the import and export of licit narcotics. It does this to prevent accumulation of narcotics that could subsequently be a risk of diversion to non-licit uses with commensurate public health risks.

**Estimate Table**

Average Annual Compliance Costs (from Business as usual)				
Costs (\$m)	Business	Community Organisations	Individuals	Total Cost
Total by Sector	\$406,966	\$0	\$0	\$407,000
Cost offset (\$m)	Business	Community Organisations	Individuals	Total by Source
Agency	\$0	\$0	\$0	\$0
Within portfolio	\$0	\$0	\$0	\$0
Outside portfolio	\$0	\$0	\$0	\$0
Total by Sector	\$	\$	\$	\$
Proposal is cost neutral? yes <b>no</b>				
Proposal is deregulatory yes <b>no</b>				
Balance of cost offsets \$407,000				

## Section 5: Consultation

Targeted consultation with States and Territories, researchers, manufacturers and Commonwealth departments has been ongoing throughout the development of the proposed options

Consultation with Commonwealth Government departments and agencies has also occurred through the Standing Interdepartmental Committee on International Narcotic Issues (SIDCINI). This committee consists of representatives from the Department of Health, Prime Minister and Cabinet, Australian Customs and Border Protection Service, Agriculture and Water Resources, Australian Federal Police, Infrastructure and Regional Development, Attorney General's, Australian Competition and Consumer Commission, Foreign Affairs and Trade, Crime Commission, and the National Health and Medical Research Council. The ongoing consultations through SIDCINI ensure that Australia's national and international policy positions are mutually reinforcing, consistent and workable.

As part of the Intergovernmental Committee on Drugs (IGCD), involving the Commonwealth, States and Territories, discussions have focussed on developing a nationally agreed approach to this issue. Without an agreed and activated national approach, there is a significant chance that individual jurisdictions will take different approaches to authorising cannabis and cannabis-derived products for medical use. Controls on the forms and uses of cannabis that differ between jurisdictions creates a significant risk of regulatory gaps that organised criminal groups would be highly likely to exploit and which may leave some patients and doctors without the access available in other jurisdictions. The IGCD have expressed the need for further research which has also been a recommendation of previous State and Territory inquiries into the use of cannabis for medicinal purposes, and is echoed nationally by key stakeholders.

Extensive consultations have been undertaken with jurisdictions over recent months. Exposure drafts have been provided to jurisdictions and consultations have been ongoing. A consultation strategy has been provided to the Minister for Health to guide discussions with parliamentary colleagues and jurisdictions prior to and at the time of the introduction of the Bill. The Department is maintaining contact with States and Territories throughout the process.

The required amendments to the Narcotic Drugs Act significantly affect both existing Commonwealth legislation and State and Territory legislation. Exposure drafts have been shared with jurisdictions for comment on 4 December 2015 and 6 January 2016. Jurisdictions have met face to face on two occasions and participated in several national teleconferences. Jurisdictions have also been contacted individually on occasions to discuss specific issues.

Overall, there is support for the Commonwealth's approach to this issue. Stakeholder feedback has focussed on the following points:

- Aligning the legislative changes to State and Territory timeframes;
- Funding of the scheme;
- Role of States and Territories on monitoring and inspection;
- Protocols for information gathering and sharing;
- Jurisdictions ability to influence licensing decisions;
- Patient access and cross border issues;

- Exporting; and
- Capacity of cultivators to grow both industrial and medicinal cannabis.

These items have been addressed with jurisdictions.

Several other key stakeholders, including the Australian Medical Association (AMA), Royal Australasian College of Physicians (RACP), Multiple Sclerosis (MS) Australia, MS Research Australia and Palliative Care Australia, have publicly expressed support for the facilitation of safe and effective access to cannabis for medicinal purposes in Australia.

The AMA supports the Therapeutic Goods Administration regulatory process where medical products are approved as a therapeutic good, with a high level of scientific evidence. The AMA also supports the approved authorised prescriber pathway under the Therapeutic Goods Act as it still requires some evidence to support the use of a particular therapeutic product. While the AMA acknowledges that cannabis has constituents that have potential therapeutic uses, it argues that:

1. appropriate clinical trials of potentially therapeutic cannabinoid formulations should be conducted to determine their safety and efficacy compared to existing medicines, and whether their long-term use for medical purposes has adverse effects;
2. therapeutic cannabinoids that are deemed safe and effective should be made available to patients for whom existing medications are not as effective;
3. smoking or ingesting a crude plant product is a risky way to deliver cannabinoids for medical purposes and other appropriate ways of delivering cannabinoids for medical purposes should be developed; and that
4. any promotion of the medical use of cannabinoids will require extensive education of the public and the profession on the risks of the non-medical use of cannabis<sup>2</sup>.

The RACP considered that ‘while medicinal cannabis shows some potential for certain patients, further research is required to determine its efficacy and it should be subject to the same scrutiny as any other medicine’<sup>3</sup>.

Both MS Australia and MS Research Australia are ‘committed to supporting the provision of proven therapies for improving the lives of people with MS, and will continue to monitor the debate regarding cannabis use for medical purposes and their potential impact on people affected by MS’<sup>4</sup>.

Palliative Care Australia believes ‘there is a place for medicinal cannabis in medical treatments and palliative care for specific symptoms. There are patients and doctors who strongly stand by its use;

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<sup>2</sup> AMA Position Statement – Cannabis Use and Health – 2014, 1 May 2014 (<https://ama.com.au/position-statement/cannabis-use-and-health-2014>)

<sup>3</sup> Submission to Senate Inquiry in the Regulatory of Medicinal Cannabis Bill 2014 ([www.aph.gov.au/sitecore/content/Home/Parliamentary\\_Business/Committees/Senate/Legal\\_and\\_Constitutional\\_Affairs/Medicinal\\_Cannabis\\_Bill/Submissions?main\\_0\\_content\\_1\\_RadGrid1ChangePages=3](http://www.aph.gov.au/sitecore/content/Home/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill/Submissions?main_0_content_1_RadGrid1ChangePages=3))

<sup>4</sup> Submission to Senate Inquiry in the Regulatory of Medicinal Cannabis Bill 2014 ([www.aph.gov.au/sitecore/content/Home/Parliamentary\\_Business/Committees/Senate/Legal\\_and\\_Constitutional\\_Affairs/Medicinal\\_Cannabis\\_Bill/Submissions?main\\_0\\_content\\_1\\_RadGrid1ChangePages=3](http://www.aph.gov.au/sitecore/content/Home/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill/Submissions?main_0_content_1_RadGrid1ChangePages=3))

however, what is needed, as is the case for any medications, is a strong evidence base and not only anecdotal stories'<sup>5</sup>.

Two industry groups (Medicann and AusCann) have also made public their views in regards to the need to facilitate safe and effective access to cannabis for medicinal purposes in Australia. Medicann believe that 'medicinal cannabis should not be regulated by the current system (TGA)'. They argue that cannabis is a natural product and should be treated as such when it comes to the regulation of its use as a medicine or therapeutic good<sup>6</sup>. AusCann state that 'it is critical that dried medical cannabis is treated as much as possible like a medication by creating a licensing scheme for the commercial production and distribution of dried cannabis for medical purposes'<sup>7</sup>.

Existing manufacturers licensed under the Narcotic Drugs Act have been made aware of the proposed changes, as there are consequential amendments proposed to the manufacturing provisions, including the application of a 'fit and proper persons' test for the first time. They are broadly understanding of the need for these changes and do not anticipate significant difficulty in complying. However, there has not been sufficient time to formally consult. Existing licences will continue under the previous conditions until they lapse, some as late as December 2018, so there is time for the Department of Health to continue dialogue with them to minimise any impact.

## Section 6: Recommended Option

If Option 1, maintain the status quo, were chosen and some States/Territories proceeded to enable cultivation unilaterally, the Commonwealth would be considered non-compliant with the INCB and in breach of its international obligations under the Single Convention. Victoria introduced legislation to this effect to its Parliament in December 2015 and indicated that it would enact its legislation, if the Commonwealth were not to take action that had an equivalent effect. As such, the risk to Australia's compliance with its international obligations is extremely likely to be realised should Option 1 be progressed. This option may also have a negative impact on Australia's licit poppy market and consequently the global supply of licit opiates

Importantly, some Australian patients may be at risk through the use of illicit sources of product with unknown and variable properties.

Amending the Narcotic Drugs Act (Option 2) would facilitate the safe access to cannabis for medicinal purposes for patients in certain circumstances with defined conditions and the ongoing and enhanced

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<sup>5</sup> Submission to Senate Inquiry in the Regulatory of Medicinal Cannabis Bill 2014 ([www.aph.gov.au/sitecore/content/Home/Parliamentary\\_Business/Committees/Senate/Legal\\_and\\_Constitutional\\_Affairs/Medicinal\\_Cannabis\\_Bill/Submissions?main\\_0\\_content\\_1\\_RadGrid1ChangePages=3](http://www.aph.gov.au/sitecore/content/Home/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill/Submissions?main_0_content_1_RadGrid1ChangePages=3))

<sup>6</sup> Submission to Senate Inquiry in the Regulatory of Medicinal Cannabis Bill 2014 ([www.aph.gov.au/sitecore/content/Home/Parliamentary\\_Business/Committees/Senate/Legal\\_and\\_Constitutional\\_Affairs/Medicinal\\_Cannabis\\_Bill/Submissions?main\\_0\\_content\\_1\\_RadGrid1ChangePages=3](http://www.aph.gov.au/sitecore/content/Home/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill/Submissions?main_0_content_1_RadGrid1ChangePages=3))

<sup>7</sup> Submission to Senate Inquiry in the Regulatory of Medicinal Cannabis Bill 2014 ([www.aph.gov.au/sitecore/content/Home/Parliamentary\\_Business/Committees/Senate/Legal\\_and\\_Constitutional\\_Affairs/Medicinal\\_Cannabis\\_Bill/Submissions?main\\_0\\_content\\_1\\_RadGrid1ChangePages=3](http://www.aph.gov.au/sitecore/content/Home/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill/Submissions?main_0_content_1_RadGrid1ChangePages=3))

pursuit of evidence through clinical trials in a way that is compliant with Australia's international obligations while adding minimal regulation to the Australian community.

## **Section 7: Implementation**

It is proposed that the Department of Health, through the newly established Office of Drug Control, will license those who cultivate, produce and manufacture cannabis and cannabis products for medical and scientific use, while the TGA would regulate the manufacture, registration and supply of medicinal cannabis products, in the same way that it does for all other therapeutic goods. The continued involvement of the TGA in this process is essential to ensuring that these products are safe and closely monitored.

As this approach is currently undertaken for the regulation of other therapeutic goods and narcotic drugs, relevant and affected stakeholders, including the drug industry, are aware of the regulatory requirements. It is envisaged that all other powers (including the licensing of production and manufacture of cannabis products) would be covered by amendments to, or the current provisions of, the Narcotic Drugs Act along with the current provisions of the Therapeutic Goods Act, the Customs (Prohibited Imports) Regulations, the Quarantine Act and Customs (Prohibited Exports) Regulations.

Implementation will need to allow for State and Territories to be consulted and to develop and secure their schemes in a complementary fashion to a Commonwealth scheme.

## **Section 8: Conclusion**

Under Option 1, the Commonwealth is likely to become non-compliant with the Single Convention where States and Territories proceeded to allow cultivation unilaterally. Further, patients will continue to access illicit and potentially dangerous unregulated supplies, exposing themselves to health risks.

Based on qualitative assessment of the options, the highest net benefit to the Australian community would be to facilitate the safe and effective access to cannabis for medicinal purposes by amending the Narcotic Drugs Act. This option will allow Australia to develop a safe, legal and sustainable local supply of cannabis for medicinal or scientific purposes. In turn, this will support greater local opportunities to research, develop, manufacture and supply cannabis for therapeutic products. Other benefits of a local cultivation include a potential new agricultural industry within Australia, similar to that already established for the use of Australian-grown poppies for medicinal and scientific purposes.

In addition, allowing Australia to cultivate legal cannabis crops for medicinal use under strict local controls strikes the right balance between patient access, community protection and our international obligations.

## Attachment A

### Australian State and Territory Legislation

Providing penalties for possessing, using, making or selling or driving under the influence of cannabis

<b>Jurisdiction</b>	<b>Legislation</b>
<b>New South Wales</b>	<i>Drug Misuse and Trafficking Act (1985)</i> New South Wales Government laws – General
<b>Australian Capital Territory</b>	<i>Drugs of Dependence Act (1989)</i> <i>Criminal Code Regulation (2005)</i> Australian Capital Territory Government laws – General
<b>Tasmania</b>	<i>Misuse of Drugs Act (2001)</i> <i>Interpretation: Poisons Act (1971)</i> Tasmanian Government laws – General
<b>Western Australia</b>	<i>Cannabis Law Reform Act (2010)</i>
<b>Victoria</b>	<i>Drugs, Poisons and Controlled Substances Act (1981)</i> <i>The Therapeutic Goods (Victoria) Act (2010)</i> Victorian Government laws – General
<b>Queensland</b>	<i>Drugs Misuse Act (1986)</i> <i>Police Powers and Responsibility Act (2000)</i> Queensland Government laws – General
<b>South Australia</b>	<i>Controlled Substances Act (1984)</i> <i>Section 33L of the Controlled Substances Act (1984)</i> <i>Summary Offences Act (1953)</i> South Australian Government laws – General
<b>Northern Territory</b>	<i>Misuse of Drugs Act</i> Northern Territory Government laws – General

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**ARTICLE 5**

**The international control organs**

The Parties, recognizing the competence of the United Nations with respect to the international control of drugs, agree to entrust to the Commission on Narcotic Drugs of the Economic and Social Council, and to the International Narcotics Control Board, the functions respectively assigned to them under this Convention.

Reporting to the International Narcotics Control Board

**ANNUAL ESTIMATES OF REQUIREMENTS FOR NARCOTIC DRUGS, MANUFACTURE  
OF SYNTHETIC DRUGS, AND CULTIVATION OF THE OPIUM POPPY, THE CANNABIS PLANT AND THE COCA  
BUSH**

**Single Convention on Narcotic Drugs of 1961: articles 1, 12 and 19.**

**1972 Protocol amending the Single Convention on Narcotic Drugs of 1961:**

**articles 5 and 9.**

***Part VI:* This part concerns Governments of countries and territories that authorize the cultivation of the cannabis plant for the production of cannabis for medical and/or scientific purposes.**

22. The information furnished should include the geographical location of land used for the cultivation of cannabis and the area estimated to be in use for the cultivation of cannabis during the calendar year to which the estimates relate, regardless of whether the sowing takes place in that year or in the preceding year. Geographical locations should be reported as precisely as possible, indicating state/province and county/municipality. Areas should be expressed in hectares (1 hectare is equal to 10,000 square metres).

**Annual estimates of requirements for narcotic drugs  
(for all countries and territories)**

Narcotic drug	1		2						3		4	
	Quantity to be consumed for domestic medical and scientific purposes		Quantity to be utilized for the manufacture of:						Quantity to be added to special stocks		Quantity to be held in stocks at 31 December of the year to which the estimates relate	
			(a) Other drugs		(b) Preparations included in Schedule III of the 1961 Convention		(c) Substances not covered by the 1961 Convention					
					Regardless of whether these other drugs, preparations or substances are intended for domestic consumption or for export							
kg	g	kg	g	kg	g	kg	g	kg	g	kg	g	
Cannabis												

**Annual estimates of cannabis production**

**(for Governments of countries and territories where the cultivation of the cannabis plant is authorized for the production of cannabis for medical and/or scientific purposes)**

	I	II	III
Cultivation of the cannabis plant	Geographical location of land used	Area used for the cultivation of the cannabis plant	Total estimated quantity of cannabis to be obtained in the country
		Hectares	Kilograms
1. For the production of cannabis for medical purposes			
2. For the production of cannabis for scientific purposes			

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ARTICLE 23

*National opium agencies*

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:
  - (a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
  - (b) Only cultivators licenced by the Agency shall be authorized to engage in such cultivation.
  - (c) Each licence shall specify the extent of the land on which the cultivation is permitted.
  - (d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
  - (e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.
3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

## ARTICLE 28

### *Control of cannabis*

- 1.** If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.
- 2.** This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.
- 3.** The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.