Australian Government
Department of Health

Ministerial Submission Standard

MS16-001601
Version: (0)
Date sent to MO:<dd/mm/yy>

To: **Minister Sussan Ley**

cc: **Martin Bowles PSM**
s22

Subject: **Medicinal Cannabis Regulatory Scheme**

Purpose: **Following our meeting on 27 July, to confirm your advice on certain policy principles to direct the Medicinal Cannabis Scheme; and seek your policy approval to develop the amendments the *Narcotic Drugs Act 1967* (the ND Act) and the *Therapeutic Goods Act 1989* (the TG Act), develop the regulations to the ND Act, and develop the Charges Bill for annual charges to licences granted under the ND Act.**

Critical Date: 15 August 2016

Reason: **Enable the drafting of the Narcotic Drugs Regulations 2016 and amendments to the ND Act and TG Act by the Office of Parliamentary Counsel. 'T' status has been sought for the amendments to the ND Act and the proposed Narcotic Drugs (Licence Charges) Bill.**

Recommendations: That you:	
1. AGREE key principles supporting the design of the Scheme: **a) the ND Regulations and associated guidelines will outline security principles to prevent diversion of crop to illicit use, but not specifically mandate indoor cultivation.** **b) products made available to patients will be manufactured to appropriate quality standards.**	**1.** **a) Agreed / Not agreed / Please discuss** **b) Agreed / Not agreed / Please discuss**
2. NOTE that we will provide an analysis of options of cost recovery for the Scheme later in August.	**2. Noted / Please Discuss**
3. AGREE to give your policy approval in relation to: **a) a number of amendments to the *Narcotics Drugs Act 1967* and one (related) amendment to the *Therapeutic Goods Act 1989* and** **b) the development of a Narcotic Drugs (Licence Charges) Bill,** **both of which are proposed to be introduced and passed during the Spring Sitting of Parliament ('T' status has been sought).**	**3. Agreed / Not agreed /Please Discuss**

4. AGREE to give your policy approval in relation to the development of the Narcotic Drugs Regulations 2016 (proposed ND Regulations). **5. NOTE that we will submit the proposed Regulations to you for approval later in August.** Signature: …… …../…../2016			**4. Agreed / Not agreed / Please discuss** **5. Noted / Please Discuss**
Contact Officer:	*Bill Turner*	*Assistant Secretary, Office of Drug Control*	s22
Clearance Officer:	*John Skerritt*	*Deputy Secretary, Health Products Regulation Group*	*Clearance Officer Signature* …../…../2016

Key Issues:

1. The operation of the Scheme will need to strike a balance between medical, law enforcement and industry facilitation outcomes. This is reflected in the breadth of views provided to Government and the Department around requirements for security, infrastructure and medicinal cannabis cultivation.

Indoor versus outdoor cultivation

2. There is some disagreement between stakeholders over whether indoor or outdoor cultivation is optimal. We propose an approach that sets out security and quality principles, without mandating indoor cultivation.

Product quality

3. That products will be manufactured to appropriate standards is central to the policy on medicinal cannabis. To achieve this, manufacturing quality standards will be set under Good Manufacturing Practice (GMP) using the same model that is applied to the manufacture of any medicine used to treat serious illness.

Cost recovery

4. One of the key principles of Commonwealth cost recovery policy is that entities should generally set charges to recover the full cost of providing regulatory activities from the regulated industry. A set of New Policy Proposals outlining cost recovery options (full, partial and nil) are currently under discussion with the Department of Finance and will be submitted to the Minister for Finance for policy approval through you later this month.

5. To provide adequate notice to industry and applicants to the Scheme, this will require Regulations to have been made by the Governor-General on advice by the Federal Executive Council no later than late September.

Regulations

6. We are in the process of drafting supporting regulations for the legislation. These regulations will cover such matters as application information and documentation requirements, security, matters that must be in a contract between cultivator and manufacturer, processes for suspending a licence and requirements for persons to be a 'suitable person' to be employed in a medicinal cannabis enterprise.

Legislative bid

7. A Charges Bill will be required to enable the setting of annual charges to be applied to licences.
8. In addition, there are a small number of amendments to the ND Act that will be introduced into the Spring Sitting of Parliament. The amendments include a proposed framework for the protection of sensitive law enforcement information provided to the Secretary (in practice, his delegate) by Commonwealth, State and Territory agencies as part of decision making under the ND Act. Consequential amendments may also be required.
9. It is recommended you provide policy approval for the Charges Bill and for these legislative amendments to the ND Act and the TG Act to allow progression of drafting of the two Bills.

Background

Indoor versus outdoor cultivation

At our 27 July meeting, we discussed whether indoor/greenhouse cultivation should be prescribed in the Regulations; or alternatively whether those Regulations only should put down principles that would encourage such an outcome, but still allow industry to apply innovative solutions to business needs.

At our meeting, you agreed that Regulations should not mandate indoor or glasshouse growing, but rather establishing strong security principles, including requirements to prevent crops from being easily seen by the public, preventing unauthorised access to the property and allowing for ongoing monitoring of the site, would allow industry an appropriate degree of flexibility while managing diversion risk.

At the recent Law Enforcement Working Group meeting, members from State and Territory and Commonwealth agencies indicated a clear preference for indoor growing for security reasons. Members also acknowledged that taking a risk based approach could meet security principles in a range of environments.

Some stakeholders claim that outdoor cultivation will lower costs and produce a superior product, while other studies have shown that higher yields and greater consistency can be obtained through indoor or glasshouse cultivation. The Department is undertaking some cost modelling around production techniques and scale, which will include, but not be limited to, sensitivity to regulatory costs, the outcomes of which will be provided in a later brief.

Product quality

GMP is regulated and a GMP licence is granted under the *Therapeutic Goods Act 1989.*

Specific quality standards and interpretive guidelines for applying GMP specific for medicinal cannabis products are to be developed, albeit adapted from the Complementary Medicines guidelines. Noting that there may be a need for specific Product Quality Requirements, for example provision for analysis of each product batch for THC and CBD content.

These quality standards and guidelines will subsequently be used to guide product requirements through contracts between the manufacturer and the cultivator.

Note that manufacturers of drugs, including those for medicinal cannabis products, will require a manufacture licence under the *Narcotic Drugs Act 1967* (the ND Act) consistent with Australia's obligations under the *Single Convention on Narcotic Drugs 1961*. An appropriate guidance document will address these requirements. Some states and territories may also require additional manufacturing licences.

Cost recovery

Analysis of the end to end full cost recovery to process and administer the Scheme suggests that the cost for a cultivation licence and associated permits will be between $61,750 and $74,890 per applicant per annum. We note that a decision of the extent of cost recovery is still to be made by government.

Licence and permit applications are direct fees and will be outlined in the Regulations. The authority to impose annual charges on licences granted under the ND Act would be implemented in a separate primary legislation as annual charges are considered taxes. The relevant provisions will be set out in the proposed Narcotic Drugs (Licence Charges) Bill 2016, and the levels of licence charges will be set out in the associated Charges Regulation.

The difference in costs for a cultivation licence and permits (between $61,750 and $74,890) relates to the number of permits required and necessary variations to licence and permit conditions. The costs include a combination of fees (direct charges based on service) and charges (costs spread across industry). A breakdown of fees and charges based on effort calculations includes:

- Licence application: $5290
- Permit application: $1900
- Inspections: $21,060
- Annual charge: $33,500
- Variations and subsequent permits (if required): $13,140

Note that the above are for ND Act cultivation and research licences only, there is no current intention to charge NDA Act manufacturing fees, TGA GMP licence fees for product manufacturing are between $17,460 (for a low complexity single product manufacturing operation) through to $28,460 (for multiple or complex products).

There may potentially be some State and territory licencing fees.

Regulations drafting

To enable the operation of the legislation when it commences, it is necessary to have supporting Regulations. We are seeking your policy approval to finalise these and we will submit a Regulations package (the Narcotic Drugs Regulation 2016, Explanatory Memorandum and Explanatory Statement and Minute to the Executive Council) to you for approval following your agreement on the above principles and once drafting has been finalised by the Office of Parliamentary Counsel.

Legislative amendments

Other amendments proposed to the Act include:

a) proposed changes to the application process for licences and permits that would allow the Secretary not to consider the application if the applicant has not provided the complete package of required information and documents;

b) allow regulations to be made specifying a particular time within which a licence holder must notify the Secretary about matters specified in the regulations;

c) allow the Secretary to make guidelines and standards in relation to matters under the Act and for the Secretary to take those guidelines and standards into account when making decisions under the Act; and

d) authorise a holder of a research licence and permit to supply cannabis seeds to holders of medicinal cannabis cultivation licences.

Note that the protection of sensitive law enforcement information is a critical issue to the efficient administration of the Scheme. The Attorney-General's Department was unable to provide advice on how to achieve the outcome in time for the provisions to have been included in the Narcotic Drugs Amendment Bill 2016 that was introduced into the House in early February this year.

In addition, minor technical amendments are also proposed to the *Therapeutic Goods Act 1989* (the TG Act) relating to the Special Access Category B scheme under paragraph 19(1)(a) of that Act to form part of the Narcotic Drugs Amendment Bill 2016 (No. 2).

Relevance to Election Commitments/Budget Measures: NIL

Sensitivity: NIL

Financial Implications: NIL

Rural and Regional Considerations: Yes

Regulatory Burden Implications and/or Deregulation Opportunities:
The Scheme amends the legal and regulatory framework that currently prohibits the legal cultivation of cannabis for medicinal purpose.

Timing/Handling (including legislative changes): The Scheme comes into effect on 30 October 2016. To support that, the Bills will need to be introduced and passed by both Houses of Parliament during the Spring sittings. In addition, to enable the Regulations to come into effect, these need to be made by Governor-General on advice by the Federal Executive Council in late September 2016.

Consultations:
External stakeholders have been consulted on development of the scheme, including each State and Territory government (health departments and law enforcement agencies) and industry, clinical groups and public through public consultation and information sessions.

Australian Government
Department of Health

Information Brief

MB16-001145
Date sent to MO:<dd/mm/yy>

To: **Minister Sussan Ley**

cc: **Martin Bowles PSM**
s22

Subject: INFORMATION BRIEF: MEDICINAL CANNABIS

Purpose: To provide you with an update and talking points on the progress on the implementation of the Medicinal Cannabis Scheme

Urgency:

Clearance:

Contact Officer:	*Bill Turner*	*Assistant Secretary, Office of Drug Control*	s22
Clearance Officer:	*John Skerritt*	*Deputy Secretary, Health Products Regulation Group*	s22

Key Issues:

1. An advanced draft of the *Narcotic Drug Regulation 2016* (the Regulation) is underway with the assistance of the Office of Parliamentary Counsel.
   a. To support the cost recovery element of the scheme, policy approval on cost recovery options must be obtained from the Minister for Finance. This is necessary to allow for the inclusion of fees in the proposed regulations.
2. A draft of additional amendments to the Narcotic Drugs Act and the associated Narcotic Drugs (Licence Charges) Bill 2016 (covering the annual levy and other charges) are also under development.
3. Consultation and information sessions were hosted by the Office of Drug Control during July 2016. The meetings were held in six capital cities and were well attended with over 500 representatives from agricultural industries, research facilities, private industries, and State government representatives. A summary of the major issues raised by stakeholders is at **Attachment A**.
4. Three state and territory Working Groups have been convened to consult with the Department of Health on the framework, and initial consultation has commenced:

a. Law Enforcement Working Group comprising state and territory law enforcement agencies, the Australian Criminal Intelligence Commission (formerly the Australian Crime Commission) and the Australian Federal Police.

b. Cultivation and Production Working Group comprising state and territory governments responsible for agricultural and production, health management and transport of cannabis.

c. Patient Access Working Group, which is administered by the Therapeutic Goods Administration.

5. The Australian Advisory Council on the Medicinal Use of Cannabis is yet to be established.

6. The Medicinal Cannabis Section within the Office of Drug Control has a full complement of staff as at 20 July 2016.

7. Design specifications have been developed for a Digital Business System for the secure receipt of licence and permit applications. This system is, however, unlikely to be operational for commencement of the scheme and the application process will initially be manual.

8. An engagement for an external consultant to look at micro-economic modelling of cultivation and manufacturing costs, including sensitivity to Commonwealth policy decisions, is underway.

9. A set of talking points for your use discussing the progress of, and opportunities around, the Medicinal Cannabis Scheme are at **Attachment B**.

Background:

10. The *Narcotic Drugs Amendment Act 2016,* which amends the *Narcotic Drugs Act 1967,* received Royal Assent on 29 February 2016. Implementation requires development of a best-practice regulatory scheme that:

a. allows for legitimate patient access to cannabis therapies

b. does not constrain scientific investigation / medicinal research involving cannabis

c. minimises regulatory burden on Australian industry to meet any legitimate supply needs for medicinal cannabis while meeting Australia's obligations under the *Single Convention on Narcotic Drugs 1961.*

d. minimises the potential for medicinal cannabis dependency through overuse or abuse unauthorised and uncontrolled access, poor quality product, loss and/or diversion for illicit use.

11. This will be administered by the Office of Drug Control within the Department of Health, which is responsible for developing regulations and procedures and guidance materials.

12. Under the *Narcotic Drugs Amendment Act 2016*, licences grants authorisation to cultivate cannabis or production[1] (or both), or to manufacture medicinal cannabis products. All licences are subject to conditions, compliance and monitoring. The three types of licences relating to medicinal cannabis are:

a. Medicinal Cannabis Cultivation licence authorising cultivation and / or production

b. Medicinal Cannabis Cultivation research licence authorising similar for research purposes

c. Manufacturing licence authorising the manufacture of a drug or product .

[1] Production is the separation of the cannabis and the cannabis resin from the cannabis plant, essentially harvest.

13. Schedule 2 of the Amendment Act, which allows the Commonwealth to authorise state/territory agencies to cultivate, has commenced. Schedules 1, 3, 4, and 5 will commence on 30 October 2016. The Regulations must be ready to commence on this date, as well.

a. The Regulations will prescribe details of the information and document requirements for licence and permit applications and specify other associated matters. In addition the Regulations will cover suspensions and surrender of licences, as well as other ad hoc matters required to give effect to the licence and permit framework.

Attachments:

Attachment A Major concerns raised in public consultation and information sessions

Attachment B Medicinal Cannabis Scheme Talking Points

Attachment A - Major concerns raised in public consultation and information sessions

The main issues raised by prospective industry participants in the recent consultation included:

- Disappointment that, flowing from the data from comparable countries and a University of Sydney report that estimate that Australian patient requirements could potentially be met from a cultivation area as little as 2-10 ha, cultivation market may only accommodate a limited number of local growers. It was emphasised that the Act and regulations would not prescribe a maximum number of cultivation licences, but rather that the total cultivation quantities could not (consistently with Australia's obligations under the Single Convention) exceed requirements for manufacturing product for patients.
- Concerns that the Scheme could potentially favour big pharmaceutical companies over the potential for a start-up industry in Australia, due to its security, regulatory and quality requirements.
- Questions about the procurement and propagation of seeds (or strain variant tissue culture) and the development of new strains of cannabis. Our position is that seeds/tissue culture for propagation can only be acquired from legal sources, such as the existing industrial hemp industry or overseas medicinal cannabis systems that are deemed consistent with the Single Convention on Narcotic Drugs. It was suggested that methods for acquiring from illegal cultivations, either through law enforcement seizures or through an amnesty in which illegal cultivators surrendered their material, be explored. We have discussed through the Law Enforcement Working Group, as this is essentially a state/territory issue, and been advised that there is no simple legal avenue to allow this to happen. Legal advice is currently being sought to clarify the legality of transferring seeds from the industrial hemp industry into the medicinal cannabis one.
- Whether the Commonwealth should be proactive in bringing together cultivators and manufacturers. Some organisations interested in cultivation, particularly small farmers, expressed concern that they did not have business connections in pharmaceuticals manufacture.
    - In considering this issue, it would be difficult to avoid the risks of perceived favouritism arising from nomination of particular prospective manufacturers by the department, or to avoid the disclosure of specific cultivation locations – to manage security concerns, we intend to be discrete about locations.
    - Alternatively, the Department will direct enquiries from prospective cultivators about potential medicinal cannabis product manufacturers industry associations who have members involved in small-scale manufacture of products to complementary medicines standards (such as Complementary Medicines Australia (CMA) and Australian Self-Medication Industry(ASMI)) and/or to the Association of Therapeutic Goods Consultants (who have a number of members who specialise in product manufacture).
    - Notwithstanding, we feel that the sophisticated players who are capable of dealing with the regulatory requirements of the scheme will also be able to manage this themselves.
- The potential cost of medicinal cannabis products was raised by some. However, a significant majority of participants supported the principle you have publicly expressed

that products manufactured from medicinal cannabis would be of consistent quality and suitable for use by individuals with illness, including children.

- While it is unlikely that the cost of commercially produced quality-controlled medicinal grade cannabis products would undercut the cost of producing illicit home-grown cannabis, discussions with Canadian producers s suggest that a large number of patients are prepared to pay for quality-assured product.

- Access to medicinal cannabis product for suitable patients residing in rural and remote areas was also raised. This will be more an issue for states and territories when ensuring that locally-based pharmacies are able to dispense products.

The feedback from these consultations has been consolidated and a summary of questions and answers will shortly be provided to participants and posted at www.odc.gov.au, noting that we will be unable to provide definitive answers on specific issues until policy positions are finalised and regulations are in place.

Attachment B – Medicinal Cannabis Scheme Talking Points

The Australian Medicinal Cannabis Scheme (the Scheme) is designed to harmonise Commonwealth legislation with that in place for the states and territories, as well as meeting our obligations under the United Nations obligations of the *Single Convention on Narcotic Drugs, 1961*

The Scheme is being established to ensure that Australian patients have access to the best quality medicinal cannabis available and to ensure supply in a global environment with limited licit sources.

The medical profession is central to the decision making on whether to prescribe medicinal cannabis products, subject to state and territory legislation and the Therapeutic Goods Act.

While the Scheme does not initially allow for exports, exports are an important part of the Government's policy. The Scheme provides Australia with an opportunity to become a global and market leader in the regulation, supply and research of Medicinal Cannabis.

- Australia is establishing a world leading position through a focus on medicinal grade pharmaceutical products, which will limit the need for the consumption of raw botanical product. This is likely to be attractive to international jurisdictions seeking to supply their population with medicinal cannabis products without the issues that go with cultivation

- While the scheme does not currently allow for export, it is anticipated that once matured, Australia will have products of high value and attractiveness to other nations.

- One of the great strengths of the Australian Scheme is that it has a medicinal focus and will be supported with extensive clinical trials.

The Scheme will be tightly regulated and controlled to ensure, as much as possible, that supply to patients is uninterrupted and that diversion for illicit use is precluded.

My Department is working closely with the states and territories to support a harmonised approach and to align complex legislative arrangements. This will include the design of regulations with those stakeholders providing input, including into the specifics of the guidelines around cultivation, engagement with law enforcement, and patient access.

My Department has recently undertaken a range of public consultation sessions across Australia, with over 500 attendees in six cities. This consultation has been useful in raising policy issues and in outlining the scale and scope of the Scheme.

QB16-003

Date QTB/MB created: 5 January 2016
Last Updated by Department: 19 February 2016
Last Updated by Adviser: 27 January 2016

MEDICINAL CANNABIS

KEY ISSUES/QUESTION

- On 10 February 2016, the Commonwealth introduced the Narcotic Drugs Amendment Bill 2016 into parliament. This Bill will allow the controlled cultivation of cannabis for medicinal and scientific purposes in Australia.
- The Bill will be debated in the House of Representatives on Tuesday, 23 February with plans for its Senate introduction later that week.
- Some criticisms are that the Bill does nothing to decriminalise the possession of medicinal cannabis products. It is not necessary for the Bill to do this, since it is legal to possess medicinal cannabis products if supply has been properly authorised under the *Therapeutic Goods Act 1989* and is permitted under relevant state and territory legislation.
- It has been suggested in media (Canberra Times 11 February) that there were no legal barriers to cultivation. This is not true, cultivation of medicinal cannabis for medicinal purposes is illegal - which is why the Narcotic Drug Amendment Bill 2016 is necessary.

MINISTER'S RESPONSE LINES:

- The Government has announced that it will create a nationally-consistent licensing scheme regulating the controlled cultivation of cannabis for medicinal or scientific purposes.
- Amendments to the *Narcotic Drugs Act* will establish the authority, within the Department of Health, to regulate the cultivation of cannabis for medical and scientific use, required under the *Single Convention on Narcotic Drugs*.
- Over the past two months, there have been consultations with states and territories, Commonwealth agencies and the Greens and cross benches on an Exposure Draft of the proposed legislative changes.
- The Government recognises that providing a safe, legal and sustainable domestic supply of cannabis is a key first step in providing medicinal cannabis products that have been subject to strict manufacturing processes and assessed for standardised dosage, quality and efficacy.
- This Government is incredibly sympathetic to the suffering of those Australians with debilitating chronic pain and illnesses and we want to ensure they get access to the most effective medical treatments available
- We must ensure any therapeutic product, including medicinal cannabis, is not only a safe and effective treatment for public use, but also meets our

strict international obligations safe-guarding its manufacture and distribution for medical purposes only.

- There are already mechanisms in place to enable access to medicinal cannabis products through the *Therapeutic Goods Act 1989.* This process maintains the same high safety standards for medicinal cannabis products that apply to any other experimental or emerging medicines. While these mechanisms are available, in many cases it has been the availability of product, currently required to be imported from overseas, that has limited their use to date.
- More recently, and to complement amendments to the *Narcotic Drugs* Act, the scheduling delegate has proposed to down-schedule cannabis substances, when used in specified ways, consistent with legal cultivation and manufacture within Australia or legal import into Australia, to a Schedule 8 (Controlled drug).
- The Government's approach strikes the right balance between patient access, community protection and our international obligations.
- Cannabis is a highly regulated drug in Australia. It is important not to confuse the Government's plans with the issue of the decriminalisation of cannabis more broadly, and which is a matter for individual state and territory governments.

DEFENSIVE FACTS & FIGURES

- The introduction of the Narcotic Drugs Amendment Bill 2016 on 10 February 2016 should not affect timely access for defined patient groups. We have inserted transition provisions that will facilitate cultivation in Victoria (and any other state wishing to take advantage of the provisions) as early as July provided there is unimpeded passage through the Parliament.
- However, key aspects of access to medicinal cannabis products - including handling, transportation and storage - is controlled by their scheduling status under the *Standard for the Uniform Scheduling of Medicines and Poisons* (the SUSMP). Most cannabis products are currently listed in Schedule 9 of the SUSMP, which makes supply of product grown and manufactured in Australia very difficult and, in some states, potentially impossible.
- The scheduling delegate has proposed to down-schedule cannabis substances, when used in specified ways, consistent with legal cultivation and manufacture within Australia or legal import into Australia, to

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Cleared by:	Prof John Skerritt, Deputy Secretary, RSG		s22			s22	

Schedule 8 (Controlled drug). A public notice inviting submissions on this proposal was published on the TGA website on 21 January 2016.

- The scheduling proposal complements the Narcotic Drugs Amendment Bill 2016 and aims to simplify access for those qualified for such access, while keeping appropriate controls in place to prevent the risk of these products from being diverted to illicit uses.
- Victoria has introduced legislation into its parliament that envisages a comprehensive state controlled access scheme. Their scheme involves cultivation, which they have undertaken to remove now that the Narcotic Drugs Amendment Bill 2016 has been introduced.
- The Government is not proposing to legalise the cultivation of cannabis outside of regulated medical and scientific purposes. These legislative changes will ensure that Australia continues to comply with international obligations under the Single Convention.

BRIEF HISTORY & MILESTONES [FROM 1996]

- August 2014 – Prime Minister Abbott writes to radio host, Allan Jones, on the issue of medicinal cannabis and this was reported on air. Briefing provided to previous Health Minister Dutton.
- 21 December 2104 – New South Wales announces up to $9million for clinical trials. Commonwealth work on options to facilitate access suspended pending outcomes of trials.
- 27 January 2015 – Victorian Attorney General establishes a review of medicinal cannabis through the Victorian Law Reform Commission.
- 25 June 2015 – The Senate Committee Interim Report on the Regulator of Medicinal Cannabis Bill was received by the Senate.
- 27 July 2015 –NSW Government announced Australia's first medical cannabis trial for adults with terminal cancer will occur in NSW.
- 6 October 2015 - Victorian Premier, Daniel Andrews, announced that Victoria will legalise access to locally cultivated and manufactured medicinal cannabis for use in exceptional circumstances from 2017.
- 12 October 2015 – Greens Senator Richard Di Natale announced a bill to create a regulator for medicinal cannabis had been drafted and would be put before the Senate for a vote in November 2015.
- 17 October 2015 – You announced that you would seek parliamentary support to allow the controlled cultivation of cannabis for medicinal or scientific purposes in Australia to deliver patients access to a safe, legal and sustainable supply of locally-produced products for the first-time.
- 27 October 2015 – NSW Government announced further information on the clinical trial for children who suffer from severe epilepsy that will trial a

new cannabis-derived drug. It also announced a partnership with GW Pharma that may allow further clinical trials. A compassionate access scheme for Epidiolex® for a small number of children outside of the clinical trial was announced.

- 2 December 2015 – You announced that you woudl amend your proposal of 17 October 2015 to give control of the cultivation of medicinal cannabis to the Commonwealth.
- 10 December 2015 – An MOU was signed between Tasmania and NSW to cover Tasmanian access to clinical trials, research and cultivation of cannabis for medicinal and scientific purposes.
- 20 December 2015 – The QLD Health Minister announced a change to queensland legislation that will allow certain patients to access medicinal cannabis if granted an SAS approval or via a clinical trial.
- 21 January 2016 – A proposal to amend the SUSMP to place some cannabis-derived substances, when used in particular ways, in Schedule 8 of the Standard was published on the TGA website.
- 10 February 2016 – The Governement introduced the narcotic Drugs Amendment Bill 2016 into parliament.
- The Bill will be debated in the House of Representatives on Tuesday 23 February 2016 with plans for its Senate introduction later that week.

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Last Updated by Department: 19 February 2016
Last Updated by Adviser: 27 January 2016

BACKGROUND

- Cannabis is highly controlled drug in Australia and its use and supply is controlled by a number of laws, including the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*, the *Customs Act 1901,* the *Therapeutic Goods Act 1989* and the *Narcotic Drugs Act 1967*.
- The public debate on medicinal cannabis is emotive, centring on children with certain forms of intractable epilepsy whose parents believe that accessing illicit cannabis products is the only way of providing relief to their children and cancer patients for whom 'everything has failed' to relieve their suffering and this is 'their only hope'.
- At the Commonwealth level, Cabinet determined that access should be through pathways under the *Therapeutic Goods Act 1989*.
- Any cultivation of cannabis for supply for medicinal purposes in Australia will need to comply with Commonwealth and International obligations. These include obligations under the *Single Convention on Narcotic Drugs 1961* to establish a government body for the licensing of medicinal cannabis cultivation.
- Internationally, several countries (for example, Canada, Israel and the Netherlands) have made 'medicinal cannabis' available to certain groups of people. In the United States of America, as many as 38 states have various schemes for supply, but these are not federally sanctioned.
- On 2 December 2015, the Federal Government announced a nationally-consistent licensing scheme regulating the controlled cultivation of cannabis for medicinal or scientific purposes that will streamline the process across the country. This will be administered by the Department of Health but separately from TGA's medicines regulatory framework.
- The Narcotic Drugs Amendment Bill 2016 amends Australia's *Narcotic Drugs Act 1967* so that individual state and territory governments will not be required to put in place their own complementary legislation for cultivation. The legislation changes will also ensure Australia could be confident of its compliance with international obligations under the *United Nations' Single Convention on Narcotic Drugs 1961* (Single Convention).
- Our understanding is that only Western Australia maintains an outright ban on the use of Schedule 9 substances for therapeutic purposes. At this time, any TGA approval (Authorised Prescriber etc) does not overrule that legislation. Regardless of whether the TGA decides to reschedule cannabis as per the proposal, the Western Australian government would need to decide to adopt that decision for it to have legal effect in Western Australia. This is a limitation of the Commonwealth's powers in this area. It is understood that Western Australia is likely to reflect any decision that is made.
- We also further understand that Queensland was in a similar situation with regard to Schedule 9 but has recently amended the relevant schedule to address this.

New South Wales clinical trials

- The New South Wales government announced on 21 December 2014 that it would provide up to $9 million for clinical trials for a range of patients, including children with certain forms of epilepsy, adults with terminal illnesses and cancer patients with chemotherapy induced nausea and vomiting. This is utilising the current legal pathways through clinical trials (CTN/CTX) under the *Therapeutic Goods Act 1989.*

Victorian Legislation

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- Following a review undertaken by the Victorian Law Reform Commission, the Victorian Government introduced into parliament on 8 December 2015 comprehensive legislation that covers the cultivation, manufacture and supply of medicinal cannabis to defined patient groups.
- The Victorian Government was made aware before introducing that the elements dealing with cultivation were unnecessary and Commonwealth legislation, when enacted, would override their legislation. They have indicated that they will amend their Bill when the Commonwealth's Bill is introduced.
- As a priority, the Victorian Government will provide access to medicinal cannabis for children with severe epilepsy from early 2017. We have inserted transition arrangements into our Bill to facilitate this timeline.

Queensland Legislation Change

- Previously patients in QLD who has received an approval for the use of medicinal cannabis under TGA's Special Access Scheme (SAS) were not able to access the medication in QLD due to the requirements of the drugs and poisons legislation in that state.
- On 20 December 2015 a change to this legislation was announced which would allow access to medicinal cannabis for patients with either an SAS approval or enrolled in a clinical trial.

Scheduling of Medicinal Cannabis

- It is proposed that the SUSMP or the Poisons Standard be amended to place some cannabis-derived substances, when used in particular ways, in Schedule 8 of the SUSMP.
- Potential down-scheduling to Schedule 8 still allows very strict controls on access to the substances. A number of other therapeutically used-substances which have risk of addiction or criminal diversion such as cocaine or morphine are also included in Schedule 8.
- A public notice that allows 4 weeks for public submissions on the proposal was published on the TGA website on 21 January 2016 and the proposal will be discussed at the meeting of the Advisory Committee on Medicines Scheduling (ACMS) on 15/16 March 2016.
- Following the meeting of the ACMS in March, an interim decision will be published seeking further comment. A final decision would then be made before the end of May 2016 and published with an implementation date, if appropriate.

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Australian Government
Department of Health

Information Briefing
For Information

<MB16-000039>
Date sent to MO:<20/1/16>

To: Minister Ley

cc: Minister Nash
s22

Subject: Medicinal Cannabis Down-scheduling proposal

Purpose: To advise you of a delegate-initiated proposal to down-schedule medicinal cannabis when supplied and used in accordance with the *Narcotic Drugs Act 1967* and the *Therapeutic Good Act 1989*

Urgency: The proposal to down- schedule will be made public on 21 January 2016, in order to allow the required public consultation process to be undertaken.

Clearance:

Contact Officer:	*Bill Turner*	*Assistant Secretary, Office of Drug Control*	s22
Clearance Officer:	*John Skerritt*	*Deputy Secretary, Regulatory Services Group*	*Authorised for electronic transmission* 20/1/2016

Key Issues:

1. Cannabis and Tetrahydrocannabinols (THC) are currently in Schedule 9 of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).
2. In some states and territories, being in Schedule 9 either creates an absolute barrier to supplying and using cannabis or cannabinoids for medicinal purposes, or creates legislative and practical difficulties in the implementation of a regulatory regime. For example, Schedule 9 status may prevent handling or transport of medicinal cannabis products and the prescribing by a medical practitioner.
3. Medicines scheduling decisions are made by a senior medical officer, acting as a delegate of the Secretary of the Department. The delegate has initiated a process to consult with the states and territories and the public on a proposal to down-schedule substances in medicinal cannabis products when supplied and used in accordance with the *Narcotic Drugs Act 1967* (soon to be amended to permit the cultivation of cannabis for medicinal and related scientific purposes) and the *Therapeutic Goods Act 1989*.
4. As you know, we are currently finalising a Bill to amend the Narcotic Drugs Act for introduction in early February. The Bill, if passed by Parliament, would amend the Act to enable cultivation of cannabis for use in medicinal products to be supplied through

provisions of the Therapeutic Goods Act (clinical trials, authorised prescriber, special access scheme).

5. State and territory drugs and poisons legislation interacts with these provisions, with scheduling being a key control on access (for instance, determining whether supply of a medicine requires a prescription etc). States and territories could unilaterally schedule cannabis and other cannabinoids in a way that that would permit them to provide access; however, it is preferable that the Commonwealth provide leadership by amending the SUSMP in a manner that the states and territories could adopt in a consistent fashion. This would allow, to the extent possible, supply and access to medicinal cannabis products to be managed uniformly across the country.
6. Initial discussions with senior State and Territory Health Department representatives indicate support for the proposal that the Commonwealth down-schedule cannabis products (mostly now in Schedule 9 (Prohibited substances), although they will provide more detailed comment as part of the planned public consultations.
7. In order for potential changes to be implemented by Spring 2016, the proposal needs to be discussed at the meeting of the Advisory Committee on Medicines Scheduling (ACMS) on 15/16 March 2016. It is necessary to post a public notice that allows 4 weeks for public submissions on the proposal on 21 January 2016. The consultation period is specified in the *Therapeutic Goods Regulations* 1990.

Background:
We are currently finalising draft legislation that will enable the cultivation of cannabis for medicinal and related scientific purposes for introduction in the week commencing 8 February. The proposed amendments to the Narcotic Drugs Act will provide a comprehensive, robust and secure system for the cultivation of cannabis and the manufacture of medicinal cannabis products.

However, the supply of these products will be controlled both under the Therapeutic Goods Act and existing state and territory legislation. The primary control at the state and territory level is the Poisons Standard. Even though the Poisons Standard is a Commonwealth legislative instrument made under the Therapeutic Goods Act, it is given legal effect by states and territories through their own poisons/drugs legislation. Because of the differing structures of the relevant state/territory legislation medicines scheduling is not consistent nationally. For example, some states have allowed pathways for therapeutic use of Schedule 9 substances (which cannabis currently is), while other states have an absolute prohibition on access to Schedule 9 substances.

At least two states have proposed unilateral amendment of their schedules to enable access to medicinal cannabis as a means of facilitating access to medicinal cannabis products, but the wider view is that it would be preferable that there be a Commonwealth decision to down-schedule. This gives a better opportunity for consistent approaches and also demonstrates Commonwealth leadership.

The scheduling delegate has proposed to down-schedule cannabis substances, when used in specified ways, consistent with legal cultivation and manufacture within Australia or legal import into Australia, to Schedule 8 (Controlled drug) (the proposed public notice is at **Attachment 1**). If a down- scheduling decision is made, and adopted by those states, the effect of this would be to remove existing state prohibitions (and provide more flexibility in state controls). It would also have the effect of better enabling patients prescribed with a medicinal cannabis product in a state/territory to travel interstate without the risk of breaking criminal laws, depending on the state/territory legislation.

The proposed change to scheduling will be integrated with additional controls over cannabis, extracts derived from botanical cannabis and THC, including the requirement for Australian produced/manufactured medicinal cannabis products to be manufactured in accordance with the Narcotic Drugs Act (as proposed to be amended).

Imported products would need to be imported in accordance with the Customs (Prohibited Imports) Regulations 1956, which requires an importer to be licensed.

In addition, we are seeking public comment on the following possible additional controls:

- limiting prescribing to state/territory authorised medical practitioners; or
- limiting access to through a clinical trial, Special Access Scheme Category B or Authorised Prescribers, access routes allowed under the Therapeutic Goods Act; or
- creating a new entry 'Poisons available only from or on the order of a specialist physician'.

The final decision on the proposal will be informed by a four week public consultation and discussions at the ACMS meeting 15/16 March 2016. The expected timeline is as follows:

- Public notice - 21 January
- Public submissions submitted by 18 February
- ACMS meeting - 15/16 March
- Interim decision with proposed implementation date made public with request for submissions on the interim decision – early April
- Submissions on interim decision submitted by 2 weeks from publication of interim decision – 2 weeks after publication of interim decision
- Publication of final decision and implementation date – early May
- Implementation date (when in the Poisons Standard) could be 1 June 2016.

This would allow a decision to be made in a time that is consistent with the expected commencement of the operation of the new provisions in the Narcotic Drugs Act for cultivation (particularly in Victoria) around September/October 2016.

The final operation of the decision will depend on the time taken for states and territories to adopt the changes. Some states directly reference the Poisons Standard so adoption is automatic; while for others, regulatory change is needed to give the decision effect. The additional controls might also require state/territory regulatory changes.

Questions and Answers about the proposal for public communication are attached. These have been reviewed by the Department's media advisor. .

Attachments:

Attachment 1. Public notice

Attachment 2. Questions and Answers on Cannabis Down Scheduling Proposal

Attachment 1

Scheduling proposal for cannabis – Public notice

Proposal to enable appropriate access to medicinal cannabis products by creating new Schedule 8 entries for the following substances for internal human therapeutic use:

- Cannabis (plant and flowering tops),
- Botanically derived extracts (or derivatives) of cannabis, and
- Tetrahydrocannabinols (THC) botanically derived from cannabis.

including when prepared or packed for therapeutic use, and where the substances:

- have been produced or manufactured in accordance with the *Narcotic Drugs Act 1967*; or
- have been imported in accordance with the *Customs (Prohibited Imports) Regulations 1956.*

except when included elsewhere in Schedule 8 or Schedule 4.

Cannabis and THC would remain Schedule 9 substances:

- for human therapeutic use when it does not fit the above criteria, or
- when not for human therapeutic use, or
- Does not fit any other current exceptions.

Options for additional controls on these substances through an entry in Appendix D of the SUSMP could include one of the following:

- restriction of access to state/territory authorised medical practitioners (current Item 1 - Poisons available only from or on the prescription or order of an authorised medical practitioner); or
- restricting access to :
    - clinical trials conducted under the TG Act when unapproved products including these substances are used i.e. Clinical trial Notification (CTN) or Clinical Trial Exemption (CTX); and
    - supply as an unapproved product through the TGA Special Access Scheme Category B or the Authorised Prescriber Scheme similar to the current Item 3 (Poisons 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 under section 19 of the *Therapeutic Goods Act 1989*.); or
- restricting access by creating an entry such as "Poisons available only from or on the order of a specialist physician".

Attachment 2

Cannabis re-scheduling proposal – Questions and Answers

What is proposed?

It is proposed that the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP or the Poisons Standard) be amended to place some cannabis-derived substances, when used in particular ways, in Schedule 8 of the Standard.
Potential down-scheduling to S8 still allows very strict controls on access to the substances. A number of other therapeutically used-substances which have risk of addiction or criminal diversion such as cocaine or morphine are also included in schedule 8.
Cannabis and THC (a psycho-active component of cannabis) currently sit in Schedule 9, which means access for their use is extremely restricted.

Why is this being proposed?

On 17 October 2015, the Commonwealth Government announced that it will seek parliamentary approval of amendments to the *Narcotic Drugs Act 1967* to establish a national scheme to allow the cultivation of cannabis for medicinal purposes. However, the access to these products - including handling, transportation and storage - is controlled by their scheduling status under the Poisons Standard. Most cannabis products are currently listed in Schedule 9 of the Poisons Standard which makes supply of product grown and manufactured in Australia very difficult and, in some states, potentially impossible. This scheduling proposal **complements the planned amendments to the Narcotic Drugs Act** and aims to simplify access for those qualified for such access, while keeping appropriate controls in place to prevent these products from being diverted to illicit uses.

What is the scheduling process?

Scheduling is the national system for applying access restrictions on human and veterinary medicines as well as a range of chemicals where there is a potential risk to public health and safety. Substances are scheduled according to the degree of risk and the level of control required over availability to protect consumers.
While decisions on medicines scheduling are made by a delegate, who is a senior medical officer, in the Commonwealth Department of Health, the implementation of scheduling decisions is the responsibility of state and territory governments. The state and territory government are responsible for imposing legislative controls on the supply of substances and the controls these governments impose usually flow from the schedule in which the poison is located.
The policy is outlined in the Australian Health Ministers' Advisory Council Scheduling Policy Framework found at www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals.
The proposal will be referred to the Advisory Committee on Medicines Scheduling (ACMS) for advice, and after publication on the TGA website (www.tga.gov.au) today (21 January 2016), public comment is invited prior to committee consideration by close of business 18 February 2016.
After the Committee considers the re-scheduling proposal, public comment and background papers, they will provide a recommendation to the senior medical officer.

Does this public notice mean that substances derived from cannabis will definitely be down-scheduled?

No. The scheduling decision will be made by a senior medical officer (in the capacity as a delegate of the Secretary of the Commonwealth Department of Health). Comments are being sought prior to a meeting of the Advisory Committee on Medicines Scheduling in March 2016. The Committee is made up of independent experts as well as state and territories representatives that provide advice to the scheduling delegate. The scheduling delegate will make an interim decision based on the comments made and the advice from the Committee.

What is the role of states and territories in this?

An entry in the Poisons Standard has no legal effect unless it is adopted through state and territory drugs and poison legislation. If approved, the proposal aims to support a consistent approach that all states and territories can apply to allow the supply of medicinal cannabis in their jurisdiction. It will be up to the individual states and territories how they might wish to implement any final decision.

Why can't the *Therapeutic Goods Act 1989* be used to guarantee a consistent approach to supply of medicinal cannabis products?

The role of the Therapeutic Goods Act relates to the regulation of the supply of therapeutic goods and works in tandem with state and territory legislation on the access to scheduled particular substances. This proposal is designed to facilitate the access pathways already available under the Therapeutic Goods Act for unregistered products.
The Therapeutic Goods Act makes provision for the use of unregistered medicines in certain cases where there is medical opinion that it is justified, such as through the Authorised Prescriber Scheme, where a medical practitioner can be authorised by the TGA to prescribe a specific medicine to a specific patient group.

It also allows for the conduct of clinical trials, which are necessary to test new medicines to enable them to be registered by the TGA for general use.

When will a decision be made?

Following the meeting of the ACMS in March, an interim decision will be published seeking further comment. A final decision would then be made before the end of May 2016 and published with an implementation date, if appropriate.
However, implementation of the decision in individual states and territories will depend on when and how it the decision adopted into state and territory legislation.

QB14-054

Date QTB/MB created: 21 January 2015
Last Updated by Department: 21 December2015
Last Updated by Adviser: 2 December 2015

MEDICINAL CANNABIS

KEY ISSUES/QUESTION

- The Commonwealth is currently in the process of finalising draft amendments to the *Narcotics Drugs Act 1967* to allow the controlled cultivation of cannabis for medicinal and scientific purposes in Australia.
- Amending Australia's Narcotic Drugs Act is necessary to allow Commonwealth licensing of the cultivation of cannabis in Australia for medicinal or scientific purposes, given Australia's international obligations under the *Single Convention on Narcotic Drugs 1961*.
- The amendments will cover legislation to enable cultivation and manufacture. Supply to patients will be under provisions of the *Therapeutic Goods Act 1989.* However, supply is also controlled by state and territory legislation and the Department is working with all states and territories to ensure as consistent access provisions as possible.
- Victoria has introduced its own legislation, as a stand alone scheme, including cultivation. This will have to be removed and we are working with them to ensure consistency with Commonwealth legislation.
- NSW has announced a number of clinical trials and is working with other states to enable access for patients outside NSW. They have an MoU with Tasmania, signed 10 December 2015.
- On 20 December 2015, the Queensland Helath Minister announced a change to QLD legislation that will allow patients given approval to use medicinal cannabis under the Therapeutic Goods Administration's special access scheme (SAS) or used in clinical trials to legally access medicinal cannabis in the state.

MINISTER'S RESPONSE LINES:

- The Government has recently announced (2 December) that it will create a nationally-consistent licensing scheme regulating the controlled cultivation of cannabis for medicinal or scientific purposes.
- This will remove the need for states and territories to implement legislation to set up individual cultivation schemes and ensure laws were constituent across the country for growers.
- The decision follows consultation with state and territory governments, and law enforcement agencies over the past month.
- The Commonwealth will amend the *Narcotic Drugs Act* to establish the authority, within the Department of Health, to regulate the cultivation of

QB14-054

Date QTB/MB created: 21 January 2015
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cannabis for medical and scientific use, required under the *Single Convention on Narcotic Drugs*.

- The Commonwealth will provide states and territories, law enforcement agencies and Federal parliamentarians with an exposure draft outlining the proposed legislative changes for further consultation.
- The Government recognises that providing a safe, legal and sustainable supply of cannabis is a key first step in providing medicinal cannabis products that have been subject to strict manufacturing processes and assessed for standardised dosage, quality and efficacy.
- This Government is incredibly sympathetic to the suffering of those Australians with debilitating chronic pain and illnesses and we want to ensure they get access to the most effective medical treatments available
- We also strongly support evidenced-based medicine and ensuring new treatments are clinically trialled and proven before being approved for public use.
- We must ensure any therapeutic product, including medicinal cannabis, is not only a safe and effective treatment for public use, but also meets our strict international obligations safe-guarding its manufacture and distribution for medical purposes only.
- Cannabis is a highly regulated drug in Australia. It is important not to confuse the Government's plans with the issue of the decriminalisation of cannabis more broadly, and which is a matter for individual state and territory governments.
- Our aim is to facilitate patient access to a safe, legal and sustainable supply of locally produced medicinal cannabis products, while ensuring necessary controls and safety measures are in place.
- There are already mechanisms in place to enable access to medicinal cannabis products through the *Therapeutic Goods Act 1989.* This process maintains the same high safety standards for medicinal cannabis products that apply to any other experimental or emerging medicines. While these mechanisms are available, in many cases it has been the availability of product, currently required to be imported from overseas, that has limited their use to date.
- The Government's approach strikes the right balance between patient access, community protection and our international obligations.

DEFENSIVE FACTS & FIGURES

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QB14-054

Date QTB/MB created: 21 January 2015
Last Updated by Department: 21 December 2015
Last Updated by Adviser: 2 December 2015

- The announced delay in introducing legislation should not affect timely access for defined patient groups. We have inserted transition provisions that will facilitate cultivation in Victoria (and any other state wishing to take advantage of the provisions) as early as July (or perhaps earlier) provided there is unimpeded passage through the Parliament.
- Access for defined patient groups is a matter for both the Commonwealth's Therapeutic Goods Act, as well as state and territory drug and poisions legislation. The Department is working with states and territories to negotiate, to the extent possible, consistent approaches to access that ensure relevant patients will abe able to access in all states and territories and that patients travelling interstate will not be breaching state criminal legislation.
- Victoria has introduced legislation into its parliament that envisages a comprehensive state controlled access scheme. We are confident that this will interact with the Authorised Prescriber Scheme appropriately and are working with Victoria to achieve this outcome.
- The changes announced by Queensland are a necessary step in providing access to Queensland patients. Without these changes, access is impossible, regardless of any approvals granted by the TGA.
- The New South Wales government is providing $9 million to conduct clinical trials for cannabis for a range of patients – children with certain forms of epilepsy; adults with terminal illnesses; and cancer patients with chemotherapy induces nausea and vomiting. These will be conducted
- through existing legal pathways (clinical trial notifications/ clinical trials exemptions – CTN/CTX) under the *Therapeutic Goods Act 1989*.
- Queensland, Victoria, South Australia and the ACT have announced their intention to join the NSW trials, which will allow access for eligible patients in those jurisdictions. The signing of the MoU between Tasmania and New South Wales appears to be an extension of that.
- The Australian Government is not proposing to legalise the cultivation of cannabis outside of regulated medical and scientific purposes. These legislative changes will ensure that Australia continues to comply with international obligations under the Single Convention.

BRIEF HISTORY & MILESTONES [FROM 1996]

- August 2014 – Prime Minister Abbott writes to radio host, Allan Jones, on the issue of medicinal cannabis and this was reported on air. Briefing provided to previous Health Minister Dutton.
- October 2014 – Application from Western Australian and Victorian Departments of Health to reschedule cannabidiol from schedule 9 to schedule 4. Decision made 19 March 2015, took effect on 1 June 2015.

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QB14-054

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- 27 November 2014 – A Bill was introduced to the Senate to establish an independent Regulator of Medicinal Cannabis.
- 21 December 2104 – New South Wales announces up to $9million for clinical trials. Commonwealth work on options to facilitate access suspended pending outcomes of trials.
- 27 January 2015 – Victorian Attorney General establishes a review of medicinal cannabis through the Victorian Law Reform Commission.
- 25 June 2015 – The Senate Committee Interim Report on the Regulator of Medicinal Cannabis Bill was received by the Senate.
- 27 July 2015 –NSW Government announced Australia's first medical cannabis trial for adults with terminal cancer will occur in NSW.
- 6 October 2015 - Victorian Premier, Daniel Andrews, announced that Victoria will legalise access to locally cultivated and manufactured medicinal cannabis for use in exceptional circumstances from 2017.
- 12 October 2015 – Greens Senator Richard Di Natale announced a bill to create a regulator for medicinal cannabis had been drafted and would be put before the Senate for a vote in November 2015.
- 17 October 2015 – You announced that you would seek parliamentary support to allow the controlled cultivation of cannabis for medicinal or scientific purposes in Australia to deliver patients access to a safe, legal and sustainable supply of locally-produced products for the first-time.
- 27 October 2015 – NSW Government announced further information on the clinical trial for children who suffer from severe epilepsy that will trial a new cannabis-derived drug. It also announced a partnership with GW Pharma that may allow further clinical trials. A compassionate access scheme for Epidiolex® for a small number of children outside of the clinical trial was announced.
- 2 December 2015 – You announced that you woudl amend your proposal of 17 October 2015 to give control of the cultivation of medicinal cannabis to the Commonwealth.
- 10 December 2015 – An MOU was signed between Tasmania and NSW to cover Tasmanian access to clinical trials, research and cultivation of cannabis for medicinal and scientific purposes.
- 20 December 2015 – The QLD Health Minister announced a change to queensland legislation that will allow certain patients to access medicinal cannabis if granted an SAS approval or via a clinical trial.

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QB14-054

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BACKGROUND

- Cannabis is highly controlled drug in Australia and its use and supply is controlled by a number of laws, including the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*, the *Customs Act 1901,* the *Therapeutic Goods Act 1989* and the *Narcotic Drugs Act 1967*.
- The public debate on medicinal cannabis is emotive, centring on children with certain forms of intractable epilepsy whose parents believe that accessing illicit cannabis products is the only way of providing relief to their children and cancer patients for whom 'everything has failed' to relieve their suffering and this is 'their only hope'.
- At the Commonwealth level, Cabinet determined that access should be through pathways under the *Therapeutic Goods Act 1989*.
- Any cultivation of cannabis for supply for medicinal purposes in Australia will need to comply with Commonwealth and International obligations. These include obligations under the *Single Convention on Narcotic Drugs 1961* to establish a government body for the licensing of medicinal cannabis cultivation.
- Internationally, several countries (for example, Canada, Israel and the Netherlands) have made 'medicinal cannabis' available to certain groups of people. In the United States of America, as many as 38 states have various schemes for supply, but these are not federally sanctioned. In none of these cases is medicinal cannabis supplied through the medicine regulator and products are somewhere between 'crude formulations' and 'more refined pharmaceutical products'. It is unknown how decisions on safety, quality and efficacy are taken.
- On 2 December 2015, the Federal Government announced a nationally-consistent licensing scheme regulating the controlled cultivation of cannabis for medicinal or scientific purposes that will streamline the process across the country. This will be administered by the Department of Health but separately from TGA's medicines regulatory framework.
- The proposed legislation will amend Australia's *Narcotic Drugs Act 1967* so that individual state and territory governments will not be required to put in place their own complementary legislation for cultivation. The legislation changes will also ensure Australia could be confident of its compliance with international obligations under the *United Nations' Single Convention on Narcotic Drugs 1961* (Single Convention).

New South Wales clinical trials

- The New South Wales government announced on 21 December 2014 that it would provide up to $9 million for clinical trials for a range of patients, including children with certain forms of epilepsy, adults with terminal illnesses and cancer patients with chemotherapy induced nausea and vomiting. This is utilising the current legal pathways through clinical trials (CTN/CTX) under the *Therapeutic Goods Act 1989*.
- The NSW Premier raised the possibility of expanding access to the clinical trial at the 16 April 2015 pre-COAG meeting of Premiers. As a result, Queensland and Victoria have agreed to take part in the trials.
- On 27 July 2015 the NSW Premier announced that a clinical trial of medicinal cannabis would go ahead to assess whether medicinal cannabis products can enhance the quality of life for adults with terminal cancer in their final stages of life, particularly by improving appetite and appetite related symptoms.
- On 27 October 2015 the NSW Government announced a further clinical trial of a medicinal cannabis-derived medicine in children with severe, drug-resistant epilepsy.

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QB14-054

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Victorian Legislation

- Following a review undertaken by the Victorian Law Reform Commission, the Victorian Government introduced into parliament on 8 December 2015 comprehensive legislation that covers the cultivation, manufacture and supply of medicinal cannabis to defined patient groups.
- The Victorian Government was made aware before introducing that the elements dealing with cultivation were unnecessary and Commonwealth legislation, when enacted, would override their legislation. They have indicated that they will amend their Bill when the Commonwealth's Bill is introduced.
- As a priority, the Victorian Government will provide access to medicinal cannabis for children with severe epilepsy from early 2017. We have inserted transition arrangements into our Bill to facilitate this timeline.

Queensland Legislation Change

- Previously patients in QLD who has received an approval for the use of medicinal cannabis under TGA's Special Access Scheme (SAS) were not able to access the medication in QLD due to the requirements of the drugs and poisons legislation in that state.
- On 20 December 2015 a change to this legislation was announced which would allow access to medicinal cannabis for patients with either an SAS approval or enrolled in a clinical trial.

Scheduling of Cannabidiol

- Cannabidiol is an extract of cannabis that has no psychoactive effect and is going to be used in clinical trials in the USA for the treatment of severe epileptic syndromes in children - Dravet and Lennox-Gaussaut Syndromes. Currently, cannabidiol is picked up under the Schedule 9 (S9) entry for cannabis.
- The WA and VIC Departments of Health made an application to amend the Poisons Standard with respect to cannabidiol (CBD) to include it in Schedule 4 (Prescription Medicine Only) of the SUSMP, otherwise known as the Poisons Standard.
- Following the scheduling process involving public submission and advice from the Advisory Committee on Medicines Scheduling, the Delegate made a final decision, which was be published on the TGA website on 19 March 2015.
- The decision was to include Cannabidiol in Schedule 4 from 1 June 2015 and the entry in Schedule 4 is for cannabidiol in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis. The wording of the entry involved discussion with the states and territories to ensure that the wording was implementable by them. It allows extracts of cannabis with at least 98% cannabidiol to be S4.
- Further discussions about the scheduling of cannabis are being undertaken to attempt to ensure as much as possible consistent access for all appropriate Australian patients, regardless of residence.

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