

Australian Government Narcotic Drug Amendment Bill 2016
Frequently Asked Questions
10 February 2016

1. What is the purpose of the Bill?

The Narcotic Drugs Amendment Bill 2016 (the Bill) provides a national licensing scheme to enable safe cultivation of cannabis in Australia. It strikes the right balance between patient access, community protection and Australia's international obligations under the *Single Convention on Narcotic Drugs 1961* (Single Convention).

The Bill creates a legal supply of cannabis for incorporation into medicinal cannabis products that are safe and of appropriate quality. This means patients will not have to turn to the black market for cannabis and it will ensure that there is appropriate medical supervision. When accessed in accordance with the *Therapeutic Goods Act 1989* and relevant state and territory law, patients won't be exposed to criminal prosecution or the health risks associated with products of unknown safety and quality.

2. What is the Single Convention?

The *Single Convention on Narcotic Drugs 1961* is a multilateral agreement that controls the cultivation, production, manufacture and trade of narcotic drugs for licit uses and requires parties to take appropriate action in relation to illicit uses.

It represents international consensus that many drugs need to be tightly controlled because of the risk of abuse and the associated risks to health, yet have legitimate uses in the medical field. Narcotics like morphine, codeine and oxycodone are subject to controls under the Single Convention. Australia, as the world's largest supplier of narcotic painkillers derived from poppies, has a strong reputation for good compliance with the Single Convention requirements.

3. What are Australia's international obligations for cannabis?

The obligations on Australia under the Single Convention are to control the cultivation, distribution and use of cannabis in a manner consistent with the licit uses provided for within the Single Convention. Some of the obligations are an exclusive obligation placed on the Commonwealth, representing Australia as the signatory of the Single Convention. These exclusive obligations relate to the cultivation, and anything related to cultivation, of cannabis.

Some of Australia's other obligations under the Single Convention do not need to be undertaken exclusively by the Commonwealth and can rely on state and territory legislation to ensure that Australia's overall system is secure and robust. For example, the Commonwealth has worked in tandem with Tasmania for decades and more recently Victoria, in managing the manufacturing of opiate alkaloids from poppies while the cultivation has been managed by the states.

It is important to note that the requirements for cannabis cultivation under the Single Convention (Article 23) are quite different to those for poppies grown for non-opium (alkaloids derived from concentrated poppy straw) producing purposes because of the

significantly different risks to public health from the diversion of crop. The ‘single agency’ described in Article 23 of the Single Convention will be within the Commonwealth Department of Health.

Australia must also report regularly to the International Narcotics Control Board, which oversees the implementation of the Single Convention, on quantities produced, manufactured and used, with a view to preventing stockpiling of raw material beyond national and global needs. The legislation is also designed to ensure the Commonwealth has data that will allow this obligation to be fulfilled.

4. What initiated the development of this Bill?

There are many reports that seriously ill patients, or their parents, are currently accessing black market cannabis to relieve their suffering, exposing themselves to the risk of criminal prosecution and the health risks of using products that are not regulated, and not supervised by their doctors. Accessing legal products is difficult and expensive, because they are not available in Australia and there are limited supplies internationally.

The Commonwealth Government is committed to facilitating the supply of legal, safe, quality medicinal products to appropriate patient groups where some benefit might be derived to reduce suffering. This means enabling the domestic cultivation of cannabis for use in clinical trials, scientific research and other medicinal purposes as allowed under the *Therapeutic Goods Act 1989*. To achieve this goal, it is necessary that amendments be made to the *Narcotic Drugs Act 1967*, so that Australia meets its obligations under the United Nations Single Convention. Since the Minister’s announcement on 17 October 2015, the Department of Health, in conjunction with other Commonwealth agencies and in discussion with state and territory governments, has been working on developing the amendments required to the *Narcotic Drugs Act 1967*.

5. What other consequential amendments are required from this Bill?

Consequential to the Narcotic Drugs Amendment Bill 2016 being enacted, amendments are also being made to the *Therapeutic Goods Act 1989* to include a regulation making power to provide for future flexibility, if needed, in relation to authorising medicinal cannabis supply under that Act.

Access

6. What is the Commonwealth planning to do about access to medicinal cannabis?

- The Commonwealth will amend the *Narcotic Drugs Act 1967* to establish the authority, within the Department of Health, to approve and regulate the cultivation of cannabis for medical and scientific use required under the Single Convention.
- Cannabis material cultivated in Australia may then, for the first time, be legally manufactured into products to be used to conduct clinical trials and develop therapeutic products to be used in accordance with the *Therapeutic Goods Act 1989*. These products can also be made available for patients outside clinical trial protocols through other pathways in the *Therapeutic Goods Act 1989* to access unregistered products, such as authorised prescribers.

- The Commonwealth already has sufficient legislative authority to regulate the import, export and manufacture of cannabinoids and cannabis raw material, just not the cultivation in Australia of cannabis plants for medicinal or scientific purposes.
- The Commonwealth is working with states and territories to ensure their legislation allows for access to defined patient groups.

7. Why don't we just import cannabis products?

- Because cultivation of cannabis is subject to strict international controls, the global supplies of cannabis for medicinal purposes are relatively scarce and expensive.
- This proposal 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 medicinal cannabis-based products for suitable purposes.
- Allowing the cultivation in Australia of legal cannabis crops for medicinal purpose under strict local controls strikes the right balance between patient access, community protection and our international obligations.

8. Will the use of cannabis for non-medicinal purposes still be illegal in Australia?

- Yes. Cannabis is a highly regulated drug in Australia and its use and supply is controlled by a number of Commonwealth, state and territory laws.
- States and territories determine the criminal and civil penalties related to the use, possession, cultivation or trafficking of cannabis within their jurisdictions and there are a number of federal offences related to cannabis as well.
- The Australian Government is not proposing to legalise the cultivation of cannabis outside of regulated medical purposes. These legislative amendments will ensure that Australia continues to comply with international obligations under the Single Convention in relation to cannabis for medicinal use and related research.

9. How will people be able to access medicinal cannabis?

- Medicinal cannabis will only be available when prescribed by a doctor, or as part of a clinical trial. It will not be available over the counter. Non-medical use of cannabis will still be illegal, as will its cultivation.
- The Australian Government has also made a commitment to work collaboratively with states and territories on the appropriate mechanisms to enable access to these products.
- There are already mechanisms in place to enable access to medicinal cannabis products through the *Therapeutic Goods Act 1989*, which allow for:
 - registration of products after full safety, quality and efficacy assessment
 - access through clinical trials
 - individual patient access under the Special Access and Authorised Prescriber Schemes under proper medical supervision.
- This process maintains the same high safety standards for medicinal cannabis products that apply to any other experimental or emerging medicine.
- With evidence developed from clinical trials, a prospective supplier could apply to the Therapeutic Goods Administration for registration of a product, as has already occurred in Australia for *Sativex*.

- The Australian government is not proposing to legalise the cultivation of cannabis or use of cannabis outside of regulated medical purposes.

10. Why is it important clinicians advise on the use of cannabis for medicinal purposes?

- Medicinal cannabis products are currently not available over the counter and this will remain the case.
- Like many other medications, this is because it is important for the safety of the patient that any access to medicinal cannabis products continues to be overseen and monitored by a suitably qualified clinician or in a clinical trial.
- While cannabis appears to be relatively safe, there is insufficient understanding of its ability to affect the efficacy of other medicines through drug interactions. It is also important to get adverse reports to advance our knowledge. This is allowed for as required in supply elements of the *Therapeutic Goods Act 1989*,
- It is important for the safety of patients and the community to maintain high safety standards for medicinal cannabis products and rigorous clinical controls on access to them.

11. How long will this take before products are on the market?

- Should legislative reforms occur at the Commonwealth, state and territory level, cannabis products made from Australian grown medicinal cannabis crops could be in use as early as 2017.
- The Government recognises that providing a safe, legal and sustainable Australian 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.
- A number of state and territory governments and companies in Australia want to cultivate medicinal cannabis and manufacture cannabis products. Specific provision is made in the Bill to allow the approval of state and territory agencies to carry out these functions before the licensing provisions come into effect.

12. Why can't people be provided with the cannabis now for medicinal purposes?

- They can and, in some cases, have. However, the global supply of cannabis for medicinal purpose is limited, difficult to acquire, and expensive. Further, Australian doctors do not have sufficient experience with overseas products.
- Cultivating cannabis for medicinal purposes will enhance the supply, while doctors will become more familiar with locally-produced product.

13. The proposed approach doesn't go far enough / is this just more clinical trials?

- The Government is sympathetic to the suffering of Australians with debilitating illnesses and wants to ensure they get access to the most effective medical treatments.
- This is a key first step to ensure the safety of any product that is supplied to the Australian public. These products may then be used to conduct clinical trials and develop therapeutic products to be used in accordance with the *Therapeutic Goods Act 1989*, specifically access under the Special Access and Authorised Prescriber Schemes under proper medical supervision

Enforcement and Misuse

14. How will the Government make sure medicinal cannabis products are not improperly used?

- The Australian Government has made a commitment to work collaboratively with states and territories to not only share knowledge and information on issues relating to the appropriate use of therapeutic products derived from cannabis, but to also consider health and law enforcement concerns for the control of cannabis in Australia.
- It is vital that we have a clear national licensing system to ensure the integrity of crops for medicinal or scientific purposes only. These legislative amendments allow the Government to track the development of medicinal cannabis products from cultivation to supply.
- From a law enforcement perspective, there are a number of issues requiring consideration when exploring options for access to medicinal cannabis, including:
 - ensuring secure possession and use among patients and carers
 - preventing the influence of criminal elements on 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
 - crime associated with increased diversion of controlled drugs to unauthorised use or misuse.
- Commonwealth and state and territory criminal, drugs and poisons legislations will be complementary and comprehensive to ensure all necessary controls are in place.

15. What about cannabis misuse?

- Australia has one of the highest per capita rates of illegal cannabis use in the world. Cannabis is also the most used illicit drug in Australia. According to the 2013 National Drug Strategy Household Survey, 35% of the Australian population reported using cannabis at some time in their lives, with 10.2% having used it in the last 12 months. 3.5% of Australians used cannabis in the previous week.
- Chronic cannabis use can be associated with a number of negative health and social effects, including increased risk of respiratory diseases associated with smoking, including cancer, decreased memory and learning abilities and decreased motivation in areas such as study, work or concentration.
- The Australian Government has made a commitment to work collaboratively with states and territories to not only share knowledge and information on issues relating to the appropriate use of therapeutic products derived from cannabis, but to also consider health and law enforcement concerns in the context of the Commonwealth's authority and obligations for the control of the cannabis plant in Australia.

Laws

16. What are the laws?

- Cannabis, being a narcotic drug, 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, State and Territory laws.
- These laws include the *Therapeutic Goods Act 1989*, *Criminal Code Act 1995*, *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*, the *Customs Act 1901*, the *Quarantine Act 1908* and the *Narcotic Drugs Act 1967*.
- Australia also has a number of obligations that it must fulfil with respect to the controls on a licit market in cannabis, cannabis resins and its extracts under the *United Nations Single Convention on Narcotic Drugs 1961*.
- These legislative amendments enable the Commonwealth to fulfil these international obligations.

17. How will the Commonwealth scheme interact with state and territory laws?

- States and territories will have no ability to legislate for the cultivation of cannabis for medicinal use or related research. However, existing manufacturing provisions will work in tandem, as they currently do for the poppy industry.
- Access provisions under the *Therapeutic Goods Act 1989* will work together with state and territory drugs and medicines legislation. It may be that amendments will be needed in some jurisdictions for patients to gain access.
- State and territory legislation on the scheduling of poisons for human use is also relevant and the department has notified of a proposition to down-schedule cannabis-derived substances used in certain circumstances to Schedule 8 in the Poisons Schedule to help facilitate access at state and territory level.

General cannabis background

18. What is the difference between pharmaceutical and recreational use of cannabis?

- There is a clear difference between regulated pharmaceutical products and using the cannabis herb for recreational purposes. In Australia, cannabis is included as a prohibited substance under Schedule 9 of the Poisons Schedule because it is associated with a range of harms. The Therapeutic Goods Administration has recently proposed that cannabis derived substances, when used *therapeutically* in accordance with the *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989*, be placed in Schedule 8. All other cannabis would remain in Schedule 9 and be tightly controlled.
- Enforcement of restrictions in the Poisons Schedule remains with the states and territories under local drugs and poisons legislation.