

**Narcotic Drug Amendment Bill 2016**

**Public Information Paper**

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## **Narcotic Drugs Amendment Bill 2016**

### **Purpose of this paper**

This paper provides information on changes to the *Narcotic Drugs Act 1967* to enable the cultivation of cannabis for medicinal and scientific purposes.

On 17 October 2015, the Commonwealth announced its intention to amend the Act 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*.

The Narcotic Drugs Amendment Bill 2016 (the Bill) provides the critical 'missing piece' for the Commonwealth to enable a sustainable supply of safe medicinal cannabis products to Australian patients in the future. In conjunction with established mechanisms, the amendments provide a secure supply chain from 'farm to pharmacy'.

It is important to note that the Bill does not legalise the cultivation of cannabis or use of cannabis outside of regulated medical purposes. Nor is it about making cannabis products available 'over-the-counter' or outside of a discussion with a qualified doctor or through an approved clinical trial.

The same high safety standards that are applied to any other medicine will be applied for cannabis derived products. As well, the manufacture of medicinal cannabis products will be subject to quality manufacturing requirements under the Therapeutic Goods Act 1989.

The Bill strikes the right balance between patient access, community protection and Australia's international obligations.

### **Introduction**

Patients can currently access cannabis for medicinal purposes under the supervision of their doctor; however, it is difficult to find suitable products. There is a growing community expectation that some patients, such as those with terminal cancer, multiple sclerosis and children with intractable forms of epilepsy, should have a ready source of medicinal cannabis products that their doctor can prescribe, if appropriate. While the current evidence around the use of medicinal cannabis is not strong, it is recognised that in certain circumstances access to approved treatments may provide some benefits, particularly pain relief, nausea control and increased appetite.

Currently, there are many reports that patients, and parents and carers of patients, are breaking the law by attaining 'medicinal cannabis products' from the black market. These products are not regulated and there are no guarantees of their safety and quality. This exposes these patients to health risks and the risk of criminal prosecution. Because of the criminality associated with this, decisions to use medicinal cannabis are often made without appropriate medical advice from a suitable medical specialist.

There is significant support for the use of cannabis for medicinal purposes in the broader community. From the 2013 National Drug Strategy Household Survey, 75 per cent of people would support a clinical trial of cannabis to treat medical conditions; and 69 per cent would also support a change to the legislation permitting the use of cannabis for medicinal purposes.

At the state and territory level, the NSW Government is investing in clinical trials that will explore the use of cannabis and cannabis products in providing relief from a range of debilitating or terminal illnesses; and the Victorian Government is taking steps to make medicinal cannabis products available to help Victorians in exceptional circumstances.

Currently in Australia, there are systems in place to license the manufacture and supply of cannabis-based products in Australia; however, there is no mechanism to allow the cultivation of a safe, legal and sustainable local supply of cannabis raw material.

This has meant Australian patients, researchers and manufacturers have had to try to access international supplies of legal medicinal cannabis crops and products – limited supplies and export barriers in other countries have made this expensive and difficult.

Permitting the cultivation of cannabis in Australia for medicinal purposes will help address this sourcing problem in circumstances where supply has been provided for under the Therapeutic Goods Act, for example, via clinical trials or through an authorised prescriber).

Australia also has international obligations to carefully control, supervise and report on various stages of narcotic drug cultivation, production and manufacture under the *United Nations Single Convention on Narcotic Drugs 1961* as amended by its 1972 amending Protocol (the Single Convention). The enabling legislation for these obligations is in the *Narcotic Drugs Act 1967*, which is currently administered by the Minister for Health and the Attorney-General.

With regards to cannabis, the primary obligation on Australia is to prevent cannabis cultivated for medicinal and scientific purposes being diverted to illicit uses. Further, the Commonwealth is obligated under the Single Convention to take sole legislative responsibility for licensing and determining where cultivation can take place. The Commonwealth cannot rely on state and territory legislation to fulfil its obligations.

Australia is also expected to tightly control the amount of cannabis produced so that it only meets current demand as determined by regulated access mechanisms. Accordingly, accumulation of stock will not occur under the new legislation. The Department of Health is required to report regularly to the International Narcotics Control Board at the United Nations.

The circumstances under which medicines and chemicals are accessible to consumers in Australia are determined through a classification process known as scheduling. Scheduling decisions made under the Therapeutic Goods Act are independent of Ministerial involvement. By this process, *Cannabis sativa* (cannabis) is included as a prohibited substance under *Schedule 9* of the *Standard for the Uniform Scheduling of*

*Medicines and Poisons* (SUSMP) (some extracts of cannabis and/or synthetic cannabinoids are scheduled elsewhere). This scheduling means that the manufacture, possession, sale or use of cannabis is prohibited unless approved by relevant authorities for medical or scientific research. On 21 January 2016, a proposal to reschedule specific forms of cannabis for specific uses was posted for public comment. This proposal will be considered by the Advisory Committee on Medicines Scheduling in March 2016, following public comment.

A change to the Schedules would still require prescribing to have very careful oversight, including by State and Territory authorities, but would enable prescribing in many cases.

At present, no form of cannabis can be registered for therapeutic use in Australia unless an application is made to the Therapeutic Goods Administration (TGA) with supporting data to assess its quality, safety and efficacy. Until a sponsor makes an application for registration of medicinal cannabis product, the TGA cannot register the product; however, the legislation recognises that there are some clinical situations where unregistered products should be prescribed after appropriate consideration by a medical practitioner, in consultation with a patient.

## **Narcotic Drug Amendment Bill 2016**

Although the Commonwealth currently has laws to regulate the import, export and manufacture of cannabinoids and cannabis raw material, existing legislation does not permit the cultivation of cannabis plants in Australia other than for industrial or horticultural purposes (regulated by the states and territories). In addition, existing manufacturing provisions in the Narcotic Drugs Act are inadequate to appropriately manage the risks associated with the potential for diversion of medicinal cannabis products and other narcotic drugs.

The Narcotic Drug Amendment Bill 2016 provides a legislative framework that will enable cannabis cultivation in Australia for medicinal and related research purposes. These amendments also ensure that when cultivation, production and manufacture of cannabis for medicinal purposes begins, Australia will remain compliant with its international treaty obligations as defined in the Single Convention.

The Commonwealth will control all regulatory aspects of the cultivation of cannabis for medicinal purposes through one national scheme. Manufacture will be a joint responsibility between the Commonwealth and the states and territories, which is consistent with the Single Convention obligations. Access to any cannabis products manufactured under the scheme is also a joint responsibility, with supply being controlled by provisions under the *Therapeutic Goods Act 1989* working in tandem with State and Territory drugs and poisons legislation.

The Bill does not override any state or territory legislation dealing with criminal activities associated with the cultivation and trafficking of cannabis that occurs outside the regulatory scheme it establishes.

## **Cultivation**

The Bill provides two types of cultivation licences – one that allows for the cultivation of cannabis plants for the production of cannabis for medicinal purposes; the other to authorise cultivation for research purposes related to medicinal cannabis.

For both forms of cultivation, an applicant for a licence to cultivate must be a ‘fit and proper person’, according to criteria set out in the Bill, and demonstrate that they can adequately manage the physical security of the crop.

Cultivation of cannabis carries a particularly high risk of diversion because the product can be readily used in its ‘raw’ state and is likely to be attractive to organised crime seeking to hide illegal activities under cover of a Commonwealth licence. The provisions in the Bill are designed to manage these risks.

It does this by ensuring that the applicant or licence holder (and any relevant business associates) does not have ties to criminal activity; has the financial resources to participate in the industry; and can satisfy security and other requirements of the conditions of the licence.

The combination of a licence and permit system will control the quantities and strains of cannabis that can be cultivated. Where the cultivation is for production into medicinal cannabis products for supply to patients, these permits will be managed to ensure that the amounts of product manufactured are planned in advance, relative to proposed usage, and do not exceed permitted manufacturing limits. The permit system will also allow the Commonwealth to discharge its estimate and reporting obligations to the International Narcotics Control Board.

## **Manufacturing provisions**

Additional amendments are proposed to the existing manufacturing provisions in the *Narcotics Drugs Act 1967*, which has not been substantively updated since introduced in 1967. This will deliver consistency in the requirements for a licence for manufacturing for all narcotic drugs along with ensuring regulatory best practice.

In particular, these changes introduce the same requirement outlined for a cultivation licence that an applicant/licence holder and any relevant business associates must be ‘fit and proper’. The same high standard must be applied to all parts of the cultivation and production process. To only apply a higher standard to cultivation could focus criminal activity on the other part of the production chain (manufacture), where entry is legally easier. This would seriously compromise Australia’s ability to meet its public health and international obligations.

Similarly, it would be inappropriate to limit the ‘fit and proper’ person test to just the manufacture of cannabis products. Other narcotic drugs (morphine, from which heroin can be manufactured, for example) represent significant public health risks and so a similar level of control for all narcotic drugs is necessary to protect public health.

### **Penalty Provisions**

Amendments to penalty units will ensure that the new legislation is consistent with other Commonwealth legislation. As the Narcotics Drugs Act has not been relevantly updated since 1967, this revised approach to penalties will also ensure that the penalties a sufficient deterrent. The introduction of civil penalties and their enforcement through the *Regulatory Powers (Standard Provisions) Act 2014* ensures a consistent operation of the scheme.

### **Appeals**

The decision making power to grant licences will no longer reside with the Minister for Health but with the Secretary of the Department of Health. This will allow an internal review of decisions to be undertaken by the Minister for Health, rather than through direct appeal to the Administrative Appeals Tribunal. This approach ensures applicants and licence holders will have more timely recourse in case of a dispute over decisions made by the Department. This also ensures the process is consistent with the new licensing provisions for cultivation inserted into the Act.

### **Access and Supply**

The Bill provides for a secure supply chain, from cultivation to manufacture, to product and then patient, with a medical prescriber involved, as appropriate. Product identification will occur in two ways:

- A product is defined for use in a clinical trial related to a particular condition and is supplied to patients who qualify for inclusion in the trial. This product might subsequently be supplied to patients not fitting the clinical trial protocol, through a pathway such as the Authorised Prescriber Scheme under the Therapeutic Goods Act.
- A state or territory-based access scheme identifies what product or products are to be supplied to a defined patient group. For example, the Victorian Government has proposed a medical expert committee to help identify appropriate products to be used for specified patients. Access by patients would also involve approval for supply of an unregistered product under the Therapeutic Goods Act.

Manufacturing can begin once a medicinal formulation of cannabis is identified. There are already provisions in the Narcotics Drugs Act through which manufacturing of a narcotic drug can be licensed. The Bill updates and strengthens these provisions and introduces specific requirements for the supply of manufactured cannabis products for medicinal use in accordance with the Therapeutic Goods Act.

States and territories will continue to have a central role in enabling access to medicinal cannabis products, particularly with regard to scheduling. Each jurisdiction is responsible for enacting medicines scheduling legislation. While the TGA is responsible for updating the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP or Poisons Standard), it only has legal effect when adopted into state and territory legislation. In addition, states and territories may vary how the scheduling is applied.

### ***Import and Export***

Matters relating to the import and export of narcotic products will continue to be regulated by the *Customs (Prohibited Imports) Regulations 1956* and the *Customs (Prohibited Exports) Regulations 1957*. Initially at least, cultivation will be solely for manufacture into products for use by Australian patients. The Bill allows for future regulations to be made that will allow export of cultivated cannabis; however, it is essential that the system be established and demonstrated to be robust and secure to gain confidence of the international community, particularly the International Narcotics Control Board and potential trading partners, before Australia considers allowing the cultivation and/or manufacturing of cannabis for raw material or medicinal products to be exported.

### ***State and Territory Authorisation***

The Bill provides for the Secretary of the Department of Health to authorise state and territory agencies to undertake cultivation and production activities that would otherwise only be authorised under a licence. This will take immediate effect and will allow cultivation to begin as soon as possible; with appropriate controls given some jurisdictions have indicated they will need this provision. This will facilitate the earliest possible access to a legal supply of cannabis products for medicinal use for patients in need. Other applicants for licences and/or permits will be able to apply after the adoption of associated regulations and rules, which is expected to take 6-8 months after the passage of the Bill.

### **Conclusion**

The Narcotic Drugs Amendment Bill 2016 will establish a robust and secure system for the cultivation of cannabis for medicinal and related scientific purposes, consistent with Australia's international obligations. This cultivation is the missing piece of the puzzle that will facilitate the development of products, promote scientific research into the potential uses of cannabis and raise awareness among the medical profession and patient groups about the options for treatment. Importantly, it puts the medical professional back into the decision making process to ensure better outcomes for patients, while ensuring that patients have a safe supply of product.