



## Medicinal cannabis

### **What is the Commonwealth planning to do about access to medicinal cannabis?**

- The Commonwealth intends to develop amendments to the *Narcotic Drugs Act 1967* that 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 1961* (Single Convention).
- Cannabis material cultivated in Australia may then be used to conduct clinical trials and develop therapeutic products to be used in accordance with the *Therapeutic Goods Act 1989*.
- 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.

### **Why don't we just import cannabis products?**

- 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 products.
- Other benefits of a local supply include a potential new agricultural industry within Australia, similar to that already established for the use of Australian-grown poppies for medicinal and scientific purposes.
- Allowing Australia to cultivate legal medicinal cannabis crops under strict local controls strikes the right balance between patient access, community protection and our international obligations.

### **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 changes will ensure that Australia continues to comply with international obligations under the Single Convention.

### **How will I be able to access medicinal cannabis and how is the Therapeutic Goods Administration (TGA) involved?**

- There are already mechanisms in place to enable access to medicinal cannabis products through the *Therapeutic Goods Act 1989* which allows for:
  - access under clinical trials; and
  - for individual patients, access under the Special Access and Authorised Prescriber Schemes administered by the Therapeutic Goods Administration (TGA).
- This process maintains the same high safety standards for medicinal cannabis products that applies to any other experimental or emerging medicine.
- With evidence developed from clinical trials, a prospective supplier could apply to the TGA for registration of a product, as has already occurred in Australia for Sativex.
- For the TGA, a recent report from the independent review of Medicines and Medical Devices Regulation has importantly made recommendations on how to simplify and streamline the approval processes for medicines and medical devices, ensuring Australians can access the latest treatments in a timely manner without compromising safety and quality.

### **Why is it important clinicians continue to advise on the use of medicinal cannabis?**

- 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 clinical trial.
- 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.

### **How long will this take before products are on the market?**

- 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.
- There are a number of state and territory governments and companies in Australia that have indicated a desire to cultivate medicinal cannabis and manufacture cannabis products. The Commonwealth's amendments to the *Narcotic Drugs Act 1967* will make it possible to control cultivation of legal cannabis crops in Australia and develop a local supply for the manufacturing of products.
- 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 – any delay to the process will result in a longer timeframe.

### **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 crime groups or individuals 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; and
  - crime associated with increased diversion of controlled drugs to unauthorised use or misuse.
- Commonwealth and state/territory legislation will be complementary and comprehensive to ensure all necessary controls are in place.

### **What are the next steps?**

- The Department of Health is preparing amendments to the *Narcotic Drugs Act 1967*, based on consultations and planning undertaken this year. It is anticipated that these amendments will be introduced into parliament before the end of this year and will be subject to standard legislative processes. If passed, the Department will be able to establish a process to licence controlled cultivation in 2016.

### **What are the Commonwealth, state and territory roles & responsibilities?**

- Once the Commonwealth has established the authority to permit controlled cultivation of cannabis in Australia, states and territories will need to consider their own legislative amendments should they wish cultivation of cannabis to occur in their jurisdiction.
- The decriminalisation of the possession and personal cultivation of raw cannabis for compassionate medicinal purposes is a matter for individual state and territory governments.

**ENDS**