



Commonwealth model – medicinal cannabis in Australia

Cultivation



- Currently not possible to legally grow cannabis in Australia for medicinal and scientific purposes and comply with our international obligations under the *Single Convention on Narcotic Drugs 1961* (the Single Convention) and other international drug control treaties
- Commonwealth will now establish the authority within the Department of Health to regulate the cultivation of cannabis for medicinal and scientific purposes required under the Single Convention
- Will ensure safe, legal and sustainable access to medicinal cannabis
- States, territories and companies may cultivate cannabis for clinical trials and specific patients where appropriate state and territory legislation is also in place
- Requires amendments to the *Narcotic Drugs Act 1967*

Manufacture



- There are already rules in place in Australia that allow states, territories and companies to manufacture cannabis products for clinical trials and specific patients
- Australian manufacture is regulated by the Therapeutic Goods Administration (TGA) through the *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989*
- The Commonwealth licensing scheme for cultivation, will ensure there is a safe, legal and sustainable domestic supply of medicinal cannabis raw material available for manufacture into finished products
- This process remains unchanged

Access

- There are already mechanisms in place to enable access to unregistered medicinal cannabis products through the *Therapeutic Goods Act 1989* which allows for:
 - Access under clinical trials; and
 - Access under the Special Access and Authorised Prescriber Schemes administered by the 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 occurred for Sativex
- This process remains unchanged