

## Why are families calling for an amnesty on using medicinal cannabis?

Some families have been giving their children medicinal cannabis from the illicit market because no legal source has been available to them. Many of these parents are in a situation where standard treatment for their child's condition has not been successful or may cause significant side effects.

These parents are trying to do the best for their children. This unfortunately means they may be sourcing various illicit, untested products of unknown quality and efficacy. A few of these parents are satisfied with the illicit product they are using and do not wish to change to another product that may be different to the current illicit product or cost more. These parents see an amnesty as a way to continue their current treatment.

The Queensland Government has moved, through the Medicinal Cannabis Act, to enable access to legal products as part of a treatment plan under the management of a treating medical officer.

## Why are families giving their children medicinal cannabis to treat epilepsy?

These families have children who are suffering debilitating illnesses and the parents are desperate to help their children. These families access information on the Internet and online forums that suggest the use of medicinal cannabis may be helpful for their child's condition. It should be noted that much of this information anecdotal and not scientifically verified.

## Is the government supporting these parents?

The Government has supported these parents by changing the law to enable access to a legal source of medicinal cannabis under the management of a treating medical officer to ensure that the child has the safest and best possible treatment available.

Some parents are requesting an amnesty from prosecution to give their children illicit medicinal cannabis. The issue is that an amnesty would not provide a legal source of pharmaceutical-grade medicinal cannabis for these families. Illegal products are not overseen by a treating medical officer and they remain outside of the treatment plan for these children. The Queensland Government has sought optimal safety for these families by providing an avenue where approved products from a legal source are able to be prescribed by doctors.

The cost of legal products is an issue for many of these families and that the reason why the compassionate access scheme (CAS) was commenced through Children's Health Queensland (CHQ). This trial enables access to free standardised medicinal cannabis product.

### **What does the Public Health (Medicinal Cannabis) Act 2016 do?**

The Public Health (Medicinal Cannabis) Act 2016 enables doctors in Queensland to legally prescribe TGA-approved medicinal cannabis to patients for certain conditions. These are conditions where there is sound clinical evidence that medicinal cannabis may be an effective treatment.

Both a Commonwealth (TGA) and State approval are required.

### **Is there currently a legal supply of medicinal cannabis in Australia?**

There are currently no businesses licensed by the Commonwealth Government to cultivate or manufacture medicinal cannabis products within Australia.

In order to legally access medicinal cannabis products they need to be imported into Australia.

The Commonwealth Government is now in the process of licensing cultivators and manufacturers to produce Australian medicinal cannabis products.

### **Why won't the State Government allow patients to use medicinal cannabis produced in Australia?**

Once Australia has its own medicinal cannabis products that meet the safety and production standards set by the Commonwealth Government's Therapeutic Goods Administration (TGA), the State government can approve these goods for use in Queensland patients.

The use of recreational or unregulated medicinal cannabis fails to ensure that products are both safe and effective for use with patients.

## **Can doctors prescribe medicinal cannabis now or do they need to wait for the Bill?**

Yes approved doctors can prescribe medicinal cannabis for eligible patients now due to changes made to the Health (Drugs and Poisons) Regulation 1996 (HDPR) in December 2015. Both a Commonwealth (TGA) and State approval are required.

## **What conditions is there good clinical evidence for, for the use of medicinal cannabis?**

Current evidence indicates that cannabis may be suitable to treat:

- severe muscular spasms and other symptoms of multiple sclerosis
- chemotherapy-induced nausea and vomiting
- some types of epilepsy with severe seizures
- palliative care (cachexia, nausea and vomiting, pain)

## **Can Queenslanders apply to use whole-plant medicinal cannabis?**

Yes, there are no restrictions on the form of medicinal cannabis products that may be prescribed, as long as there is solid clinical evidence for its use.

Most approvals granted under the Act will be for botanically-derived products.

## **How much will the GW Pharmaceutical product Epidiolex® cost once the compassionate access trial ends?**

Epidiolex® will remain freely available for children who are part of the compassionate access trial. When the product is registered on the Australian Register of Therapeutic Goods (ARTG), Queensland Health will subsidise the provision of Epidiolex® to those patients who were part of the compassionate access trial.

When the product is registered on the ARTG, the drug's sponsor can make application to have it listed on the Pharmaceutical Benefits Scheme (PBS). PBS listing means it would be subsidised by the Commonwealth Government.

## **Growing your own medicinal cannabis remains illegal.**

This is not an option under the Queensland Act. There are significant safety risks associated with products grown outside of the TGA framework.

Home-grown or illicit cannabis products have unknown concentrations of active ingredients and may contain potentially harmful contaminants. The strength or dose of these products will vary over time.

Current and proposed Commonwealth and State regulations are designed to ensure the supply of medicinal cannabis is safe.

The community has a right to expect that any medicine prescribed to them by a doctor is as safe as it possibly can be, when used as recommended.

Doctors must have confidence that any substance they prescribe to help treat a patient is safe. Doctors and their patients need to know that any medical product used for treatment has a predictable and reliable effect.

That's why we put controls around the approval and use of any medicine. People expect, and have a right to expect, that medicines sold to them are safe, when used appropriately. Users of medicinal cannabis products deserve the same certainty.

The measures in place at the State and Commonwealth level both help patients, and protect them.

## **Price of medicinal cannabis**

The price for medicinal cannabis products is determined by the market. Currently, commercial medicinal cannabis products are not cultivated or manufactured in Australia and must therefore be imported from overseas—usually from Canada or the Netherlands. This means the price is set by the overseas manufacturer. The cost varies greatly depending on the product, its source, shipping expenses and customs fees.

Over time an Australian medicinal cannabis industry will develop and medicinal cannabis products will become more readily available and affordable.

The Queensland Government does not plan to subsidise the cost of medicinal cannabis products. The Commonwealth only subsidises products listed on the Pharmaceutical Benefit Scheme, or PBS. Before a product is listed on the PBS, it must be registered by the TGA on the Australian Register of Therapeutic Goods.

The decision about whether a drug is listed on the PBS and the level of any subsidy is a matter for the Commonwealth.

### **What is the role of the Commonwealth? Is there duplication between relevant State and Commonwealth responsibilities?**

In Australia, responsibility for regulating medicines and poisons is shared between the Commonwealth and the States.

The Commonwealth controls what drugs may be used for therapeutic purposes and sets quality standards and individual States then regulate patient access to these drugs.

States are required to seek Commonwealth approval before a drug may be used for a therapeutic purpose in Australia. The drug must either be registered on the Australian Register of Therapeutic Goods or the Commonwealth Therapeutic Goods Administration must approve access to the drug for treatment of a particular patient or class of patient.

It should also be noted that a drug cannot be listed on the Pharmaceutical Benefits Scheme until it is listed on the Australian Register of Therapeutic Goods.