

# Cannabis prescribing in rural Australia

Should I prescribe cannabis?  
How can I prescribe cannabis?

Full attribution and many thanks to MRQ Qld for assistance in suppling slides in preparation of this presentation

Dr James Finn  
Addiction medicine Specialist

# Medicinal Cannabis...potted history



- 1<sup>st</sup> recorded medical use in 2737BC in China – rheumatism, constipation and gout
- Banned in UK in 1928
- Banned in USA 1937 – despite opposition from American Medical Association
- 1964 THC discovered by Prof Raphael Mechoulam, Israel
- 1988 cannabinoid receptors discovered in the brain (opioid receptors discovered 1973)
- 1992 – natural endocannabinoids discovered

# The banning tide changed.

- In 1996 California allowed for the prescribing of medicinal cannabis.
- Other Countries *followed suite*
- (*recreational cannabis is now legal in California*)

# Medicinal Cannabis – potted history

- Increasing interest in the roles of the various cannabinoids, terpenes and flavonoids that co-exist in the cannabis plant
- Increasing media interest sparked by reports about intractable epilepsy being controlled by medicinal cannabis – Charlotte's Webb ( originally called hippies disappointment)
- Anecdotal reports of success stories on the internet
- **High public demand for medicinal cannabis BUT limited good quality research**



# What's happening in Australia?



Overwhelming public support for the use of cannabis for medical purposes.....

BUT

What does that actually mean?????

# State of the Nation - Commonwealth

- Commonwealth government have amended legislation to allow for cultivation, production and manufacture of “home grown” medicinal cannabis
- Recent changes have allowed for importation by overseas manufacturers to be stored here in Australia and sold by wholesale – will speed up the process of accessing product
- Office of Drug Control manages applications for cultivation, manufacturing and wholesaling
- The ODC website provides information about stock held by wholesalers in Australia
- Imported products need to meet GMP standards, TGO93 and TGO77 (quality control measures)
- The “Australian Advisory Council on the Medicinal Use of Cannabis” has been formed to provide advice to the Minister for Health on issues related to medicinal cannabis including regulatory requirements.

# State of the Nation - TGA

- 2016 TGA re-scheduled cannabis, THC and CBD
- All products containing THC for therapeutic use are now **S8** provided they are cultivated and and manufactured according to the *Narcotic Drugs Act*
- Products which are 98% CBD are **S4**
- Access to supply of medicinal cannabis products is through the following TGA pathways (as with other unapproved goods) in addition to any S&T pathway
  - Special Access Scheme, Category B
  - Authorised Prescriber Scheme
  - Clinical trials



# On 29 August 2016- Parliamentary Subcommittee on medical marijuana





- Doctors I spoke to wanted:
- 1) Indemnification when prescribing an approved product to an approved person appropriately and as per guidelines.
- 2) Appropriate Guidelines
- ( Qld Health invited submissions fairly widely)

# State of the Nation – prescribing medicinal cannabis



- Some states have new legislation in place to allow for prescribing and dispensing of medicinal cannabis e.g. Queensland and Victoria
- Some states have made amendments to their medicines legislation such as NSW
- The remaining states and territories have utilised their present controlled drug legislation to accommodate the prescribing and dispensing of medicinal cannabis products

FACTSHEET

## UNREGISTERED CANNABIS-BASED PRODUCTS

NSW Health

**What is the effect of the new Regulation for unregistered cannabis-based products?**

On 1 August 2018, the Poisons and Therapeutic Goods Amendment (Controlled Non-ATC Products) Regulation 2018 (under the Poisons and Therapeutic Goods Act 1981) will take effect.

This regulation will allow states to apply to TGA Health to seek approval to prescribe certain cannabis-based products that are not on the Australian Register of Therapeutic Goods, in appropriate circumstances.

**What approvals are required before unregistered cannabis-based products can be prescribed?**

Doctors will require approval from both the Commonwealth Therapeutic Goods Administration and NSW Health before they can prescribe an unregistered cannabis-based product.

Given the risks associated in prescribing unregistered products, it is expected that prescribers will be equipped in the treatment of these cases for which the relevant product is being prescribed.

Patients considering the use of cannabis-based products should also be advised that certain unregistered products may not be appropriate for their needs.

**What are the key regulatory considerations?**

There are three main considerations for the supply of unregistered therapeutic goods, including cannabis-based products, in Australia: the national, the Australian Prescriber Scheme, and the Special Access Scheme. Each of these mechanisms is administered by the Commonwealth Therapeutic Goods Administration.

In assessing an application for a prescriber to supply or supply an unregistered cannabis-based product, the Commonwealth will consider the prescriber's expertise, the suitability of the product to meet the patient's condition, and the quality of the product.

TGA Health will consider whether the unregistered cannabis-based product is being appropriately prescribed for the patient's condition and the available evidence. Applications from prescribers to TGA Health will be assessed by a committee of medical experts.

**What unapproved cannabis-based products can now be prescribed?**

To be prescribed in Australia, a cannabis-based product must be legally produced. This means that the product must either be imported from a legal supply source or be produced according to the Customs (Prohibited Imports) Regulations 1957 in the manner legally prescribed. Australia under the terms of the Narcotic Drugs Act 1957.

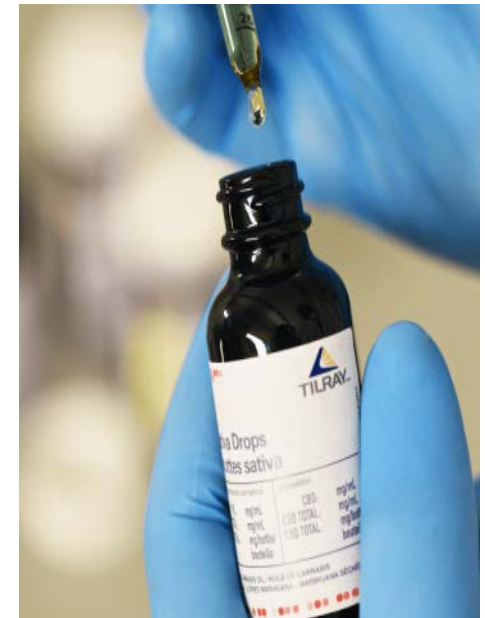
[www.health.nsw.gov.au](http://www.health.nsw.gov.au)

# State of the Nation – prescribing medicinal cannabis

- In general:
- Aim is to keep the prescribing of medicinal cannabis within the ongoing treatment plan for the patient – trying to avoid “wacky weed doctors”
- General Practitioners and specialists can prescribe except in Tasmania where it is limited to specialist only
- Qld and WA have a notification scheme as part of their process which allows certain medical specialists to notify of their intention to treat rather than applying for individual approvals/permits – may speed the process up
- All S&T’s have the provision to use an expert panel to assess applications – if needed
- Doctors generally need to have some evidence of efficacy, safety and quality when requesting approval/permit
- Most states and territories do not limit the medical condition/symptoms doctors make application for – but approval may not be granted
- Interstate prescribing may present challenges

# State of the Nation – prescribing medicinal cannabis

- Products available and allowed in all S&T's:
- Oils – available in different strengths of THC and CBD or combinations of both.
- May require cold chain management



# State of the Nation – prescribing medicinal cannabis

- Oil filled capsules and oro-mucosal sprays



# State of the Nation – prescribing medicinal cannabis

- Products for use in a vaporizer
- Generally bud or “flos”
- Smoking is **NOT** allowed in any State or territory



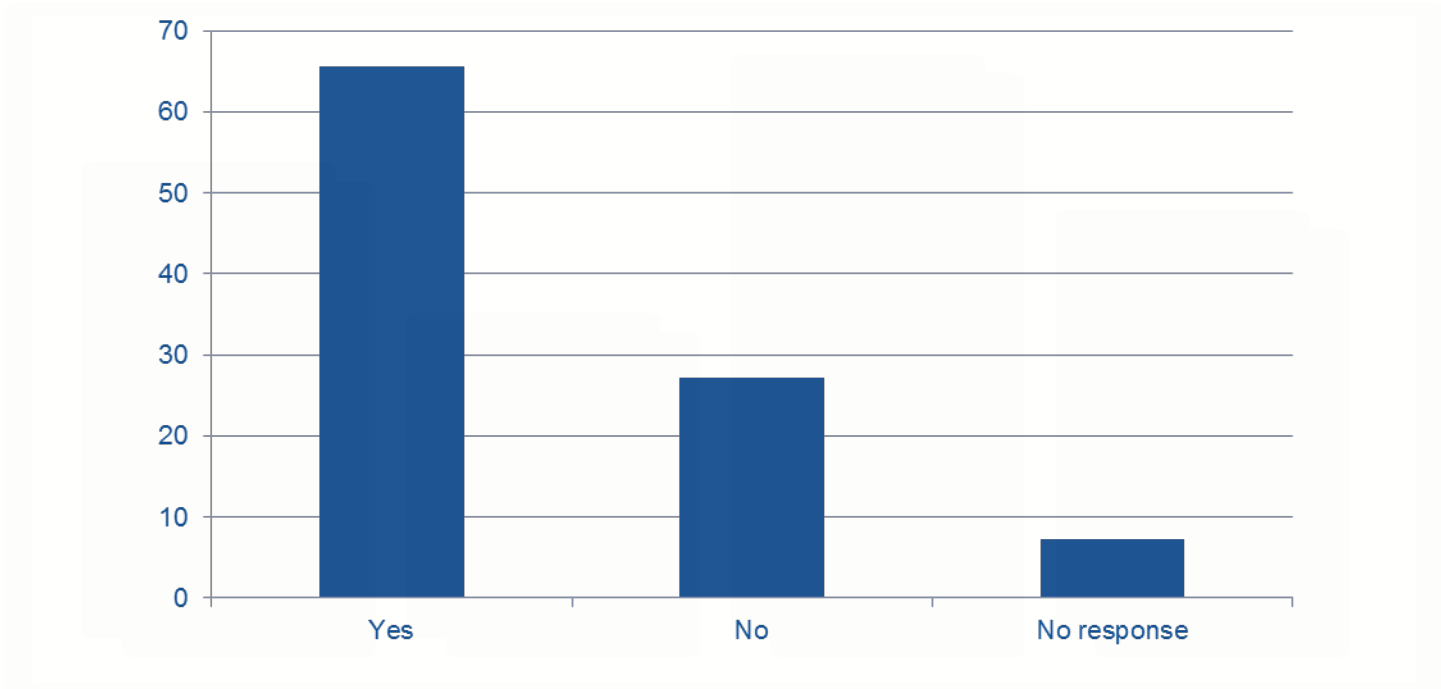
# What about Queensland?



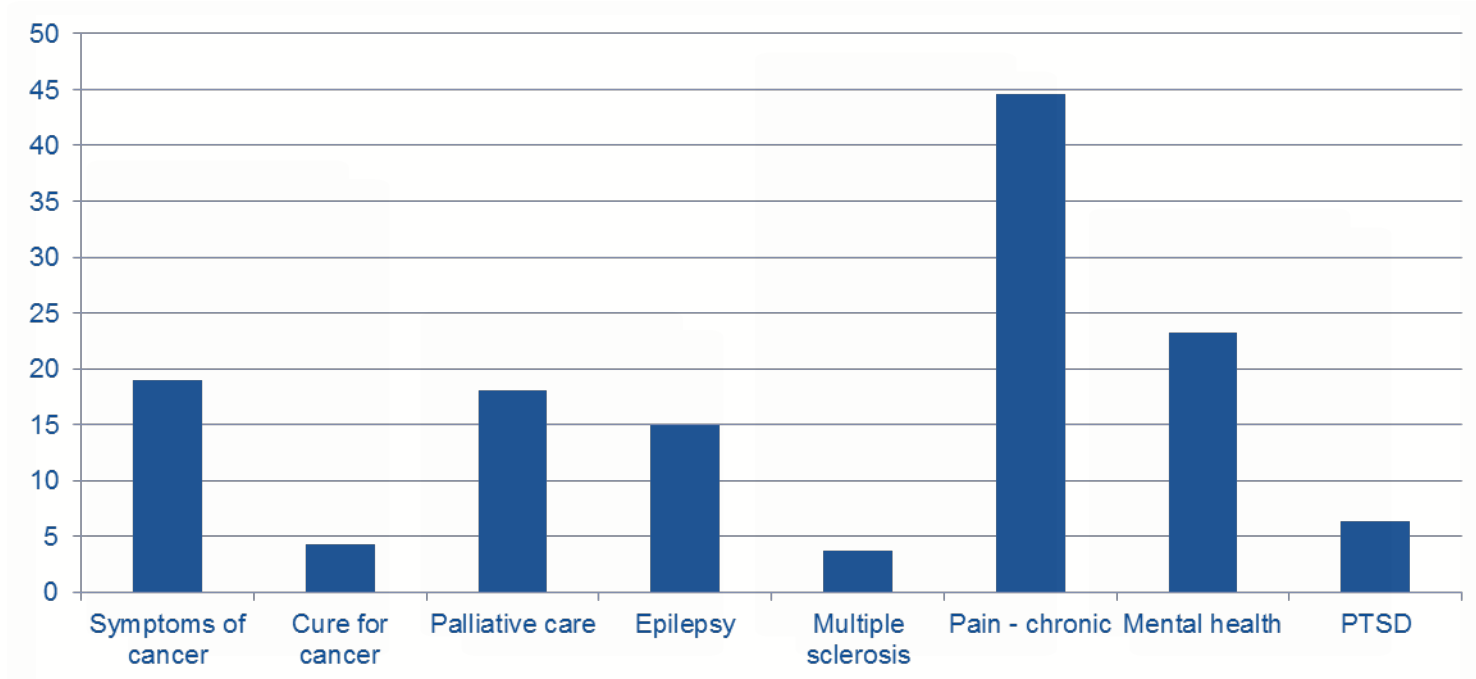


# Recent medicinal cannabis survey for doctors in Queensland

Have you had patients request medicinal cannabis for their condition/symptoms?



# What was the most common symptom/medical condition that medicinal cannabis was requested for?

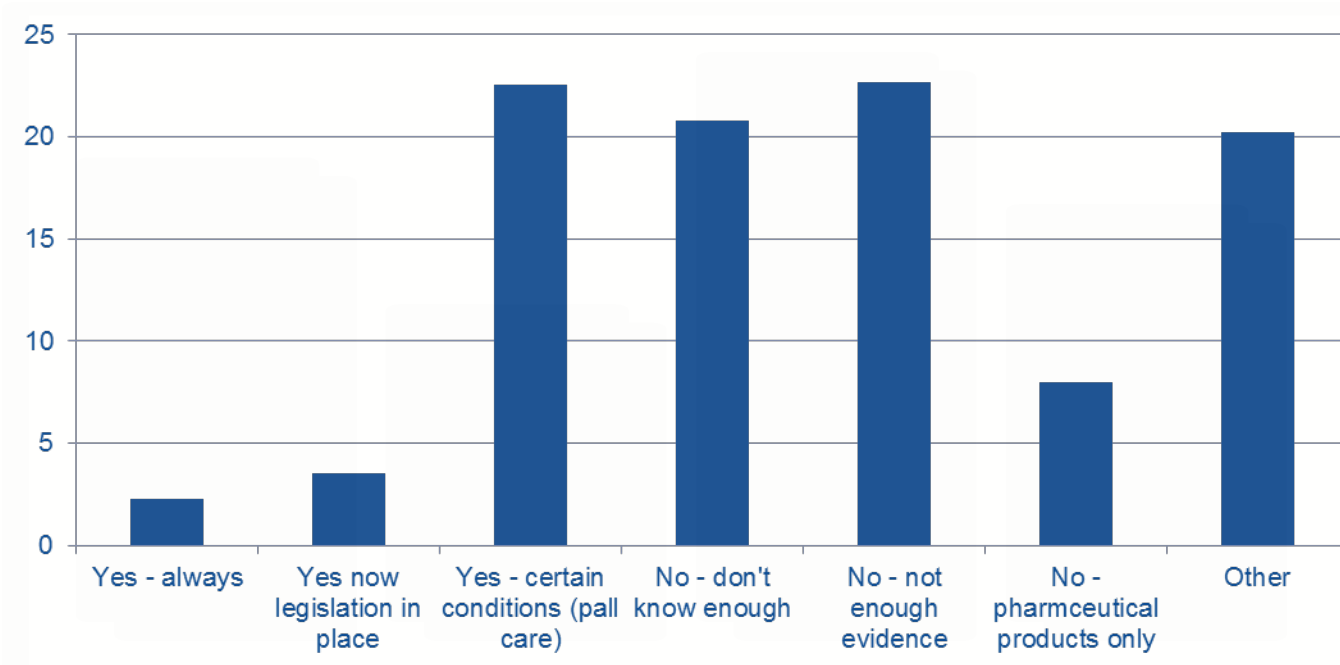


Other medical conditions included neuropathic pain, fibromyalgia, autism, COPD, anxiety, chronic fatigue syndrome

Symptoms of cancer included N&V and loss of appetite

Palliative care included any symptom associated with terminal illness

# Would you feel comfortable prescribing medicinal cannabis products?



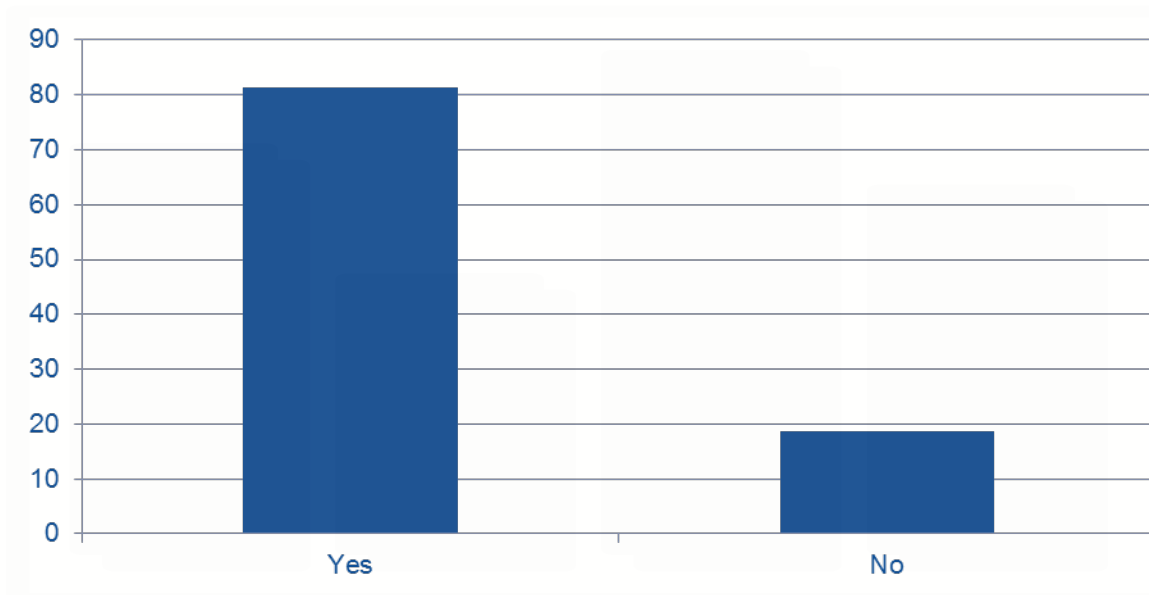
Other comments included:

Only in clinical trial setting

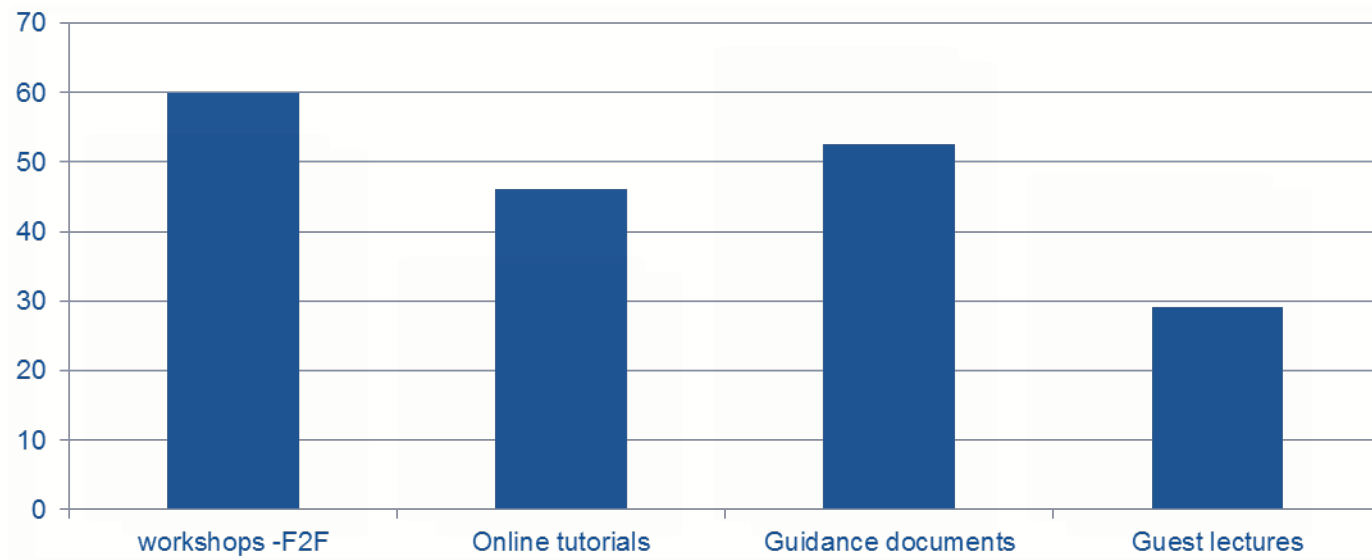
Only if all other medications had failed

Problems with cost might prohibit prescribing

**Do you believe that education and training in medicinal cannabis use would assist you to discuss this issue with your patients and possibly lead to prescribing?**



# What type of education/training do you believe would work most effectively for you?



# Results of the survey

- Highlighted much of what we already know
  - Patients are asking about medicinal cannabis use
  - As in other countries pain (in all forms) seems to be one of the main reasons for using MC
  - Generally doctors are unwilling to prescribe – for various reasons
  - Education and training may help convince some doctors to prescribe – but maybe in only some conditions?

# So We Have an Interesting Situation....

- Commonwealth has allowed for cultivation and manufacture
- S&T's have allowed for prescribing of medicinal cannabis products
- Products are available and are being stocked by wholesalers in Australia
- There is immense community expectation – including those who believe it can cure everything
- There are a number of very vocal community based action groups
- Many other countries are changing their policy on the use of cannabis as a medicine and implementing legislative change
- **But there is limited evidence about the efficacy and safety of medicinal cannabis products**
- **There are no clinical guidelines anywhere in the world especially in relation to types of products to use in each medical condition and at what dose**



# And The Wheels are In Motion.....

- So – how as this all played out in Queensland so far.....



# Since 1 March 2017 in Queensland

Activity	Number
Applications received	In total - 19 1 withdrawn 11 on hold pending further information
Approvals issued	7 6 patients received or receiving product
Referral to Expert panel	5 3 approved after Panel referral
Patient class prescribers	3 (all palliative care) Prescribed to 2 patients
Clinical trials	5 applications (4 approvals issued) 2 trials at CHQ – Zynerba and GW Pharmaceuticals 1 trial at RBWH – epilepsy 1 trial at Q-farm (completed) 1 trial - palliative care pending
Dispensing approvals	95 pharmacists working at 34 pharmacies across the state
Wholesaling	4 approvals issued for interstate wholesalers 2 approvals issued for Queensland wholesalers
Manufacturing	0 approvals

# Medicinal cannabis approvals

- **Approvals have been issued for the following symptoms/medical conditions**
  - Refractory epilepsy
  - Palliative care symptoms including loss of appetite
  - PTSD
  - Neuropathic pain – trigeminal neuralgia
  - CINV
- **Products used have included**
  - high THC,
  - equal THC:CBD mixtures
  - CBD only products
- **Product forms have included**
  - Buds for vaporisation
  - Oils
  - Topical preparations

# Helping Queensland doctors...

- Queensland is the only state to provide health professionals, especially doctors, with some initial guidance about medicinal cannabis and prescribing
  - **Clinical Guidance: for the use of medicinal cannabis products in Queensland March 2017**
  - Is available on-line and includes the only advice we can provide on dosing “start low and go slow
- Queensland has legislated additional protection for doctors who prescribe having done appropriate due diligence in determining the need for and safety of the product they have chosen
- Queensland has also mandated regular reporting by prescribers about the progress (or not) of their patients prescribed medicinal cannabis. This will add to the body of evidence around the efficacy and safety of the various products.

# Helping all doctors...

- At a national level TGA have contracted NDARC to review the evidence and provide a “National Guidance” document which will be available at the end of 2017 covering:
  - Epilepsy – children and adults – review completed
  - NV – CINV or AIDS related – review completed
  - Palliative care –control of pain and improve appetite – review completed
  - Multiple sclerosis – spasticity – review completed
  - Pain – cancer related, neuropathic and CNCP – in process
- To date the evidence is not substantial in any area
- All reviews will be available on-line

# In summary...

- The field as a whole is "too young to see evidence of the benefits," - we need to wait and learn from the wide range of “experiments” (the differing models) currently underway in different countries, including Australia.
- It will probably take about 5-10 years before we are clear about the role of cannabis has as a medicine provided research and good monitoring of patients using medicinal cannabis are able to flourish
- Legislation has provided the “*process*” for supply and access to medicinal cannabis
- Doctors have been given the role of “*gatekeepers*” but this is a role that they practice with all medicines on a daily basis
- It is still a difficult time ...
  - Balancing patients and community expectation and evidence based practice.

Once again full credit and thanks to Medicines Regulation and Quality Qld for both data and the provision of slides detailing where we are at in the Sunshine (Smart) State.