# SA Palliative Care Community Pharmacy Update

A joint initiative of South Australian Palliative Care Services

With the legalisation of medicinal cannabis, pharmacists must be aware of the current access pathways.

# **Accessing Medicinal Cannabis**

There are no medicinal cannabis products currently marketed in Australia. Overseas products can be accessed via one of the following pathways:

- > Authorised Prescriber Scheme
- > Special Access Scheme
- > Clinical trials

#### **Authorised Prescriber Scheme**

A prescriber can apply to the TGA to prescribe medicinal cannabis to specific patients or patient groups with a specified medical condition. The application must be supported by a treatment protocol approved by an appropriate ethics committee. Once approved as an authorised prescriber, no further approval is required for individual patients under this treatment protocol.

## **Special Access Scheme**

The prescriber, not necessarily a specialist, is responsible for determining whether the patient should access via Category A or B and must submit the appropriate notification or application to the TGA.

Category A is a notification only process and product is imported for a specific patient. The importation process can be complex and access may be delayed. Product already in Australia such as those reserved for Category B use cannot be used for Category A patients.

Category B decisions are generally made within five business days of receiving a completed application which must include patient specific information and evidence to support the use of medicinal cannabis for their treatment. If approved, imported stock may be already held by local wholesalers which can be efficiently supplied once evidence of approval is provided.

#### **Clinical Trials**

The study sponsors and investigators will access medicinal cannabis via the Clinical Trial Notification Scheme or Clinical Trial Exemption Scheme. These products can only be used within the study protocol.

## **Additional Licenses and Approvals**

Medicinal cannabis products may only be imported with an importation license and importation permit issued by the Office of Drug Control.

## **State Regulations**

In addition to the TGA regulations, existing state Schedule 8 legislation also applies to the prescription, storage and dispensing Schedule 8 medicinal cannabis products. Medicinal cannabis may only be prescribed by specialists with expert knowledge in the disease, so GPs must seek the advice of a specialist. A section 18A authority is required for treatment greater than two months with exemptions for those over the age of 70 years and notified palliative care patient.

#### **Useful resources**

- Medicinal cannabis, Patient access in South Australia (SA Health)
- Fact Sheet Medicinal Cannabis Products (SA Health) (188kb pdf)
- Access to medicinal cannabis products: steps to using access schemes (TGA)

## For more information

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This update is intended to provide practical up to date and factual information relating to pharmacy and medicines management in the setting of Palliative Care and is based on critical review of available evidence. Individual patient circumstances must be considered when applying this information. Please feel free to distribute this update further to interested colleagues.