



# Time to separate fact from fiction

The Australian medicinal cannabis industry is moving fast and it can be hard to tell what's real and what's rumour.

Peter Comerford, chief executive of 27-year specialised health care wholesaler and secure logistics operator Anspec, says there are three major myths around medicinal cannabis in Australia.

The first is that it is difficult for doctors to access cannabis medications. Second, that there is no solid research to guide prescribers. And third, that there is no reliable scientific information available about cannabis' safety, relative toxicity and relative addictive potential.

"The truth about access is that Australian governments have made it easier to access medicinal cannabis, especially in NSW/ACT (where the state health has agreed to work on a single approval process with the TGA). The other states are following with similar regulations through the COAG process," Comerford says.

Unregistered medicinal cannabis may be supplied where a doctor decides that for a specific patient there is a clinical need. There are two pathways, the Special Access Scheme and the Authorised Prescriber Network.

Under Special Access Scheme B, a doctor applies for TGA approval to prescribe an unregistered drug for an individual patient on a case-by-case basis.

"Doctors use SAS-B by filling out a simple form on the TGA website," Comerford says.

"TGA reviews the application and responds

within 24 to 36 hours. The medication is usually available at the pharmacy within 24 hours of the doctor getting approval.

"Apparently a recent TGA report shows 700 approvals and we see this number growing daily as new GPs, new specialties, new pharmacies and the Doctor's Colleges continue to get on board."

Using Authorised Provider Networks, TGA and state health departments approve doctors to prescribe an unregistered medicine to a group of patients, without needing to justify their clinical judgment every time they write a script.

Doctors are planning these networks to facilitate use of a particular medicinal cannabis formulation to treat a specific condition.

"The first is a network of doctors prescribing for childhood epilepsy," Comerford says.

"Others are planned by doctors treating

patients with chronic pain, chemotherapy-induced nausea, etc."

For childhood epilepsy, regulations are rapidly catching up with practice. Epidiolex, by GW Pharmaceuticals UK, was approved for this disease by the US Food and Drug Administration on June 25. "GW can use its US registration dossier in any country that has a mutual

recognition agreement with the US, including Australia," Comerford says.

Australia's positive attitude to medicinal cannabis is part of a wave of legalisations sweeping across the world, and reflects a growing body of research.

Comerford says: "A large number of government-supported trials are happening in Australia, and trials are well under way in Israel, Canada, the US.

Portugal and France have just legalised medicinal cannabis."

He points to studies published this year by researchers in Israel, in the European Journal of Internal Medicine on use of medicinal cannabis in the elderly and in patients with cancer (almost 3000 patients in each study over 10 years).

"This is expected to be the start of the Israelis' publishing program," he says.

Following a comprehensive analysis of knowledge in the field based on a government commissioned study by the National Drug and Alcohol Research Centre of the clinical evidence published in peer reviewed medical journals since 1980, the TGA site now carries bibliographies of the major studies of the use of cannabis to treat five indications: epilepsy, MS, nausea and vomiting, pain and palliation.

The TGA relied on the review in drawing up a set of guidance documents, now posted on its website, to help doctors in their clinical decisions.

As for the addictive potential of cannabis, Comerford points to a peer-reviewed study, "Acute Toxicity of Drugs versus Regulatory Status", published in *Drugs and Society: US Public Policy* (2006).

"The study places common drugs on a chart mapping toxicity against addictiveness and it speaks for itself," he says.

"It says cannabis is about as addictive as caffeine and slightly less toxic.

"Doctors know how to make good clinical decisions for their patients."

While there is disagreement within the medical profession about the wisdom of prescribing medicinal cannabis, the comfort to prescribe is rising.

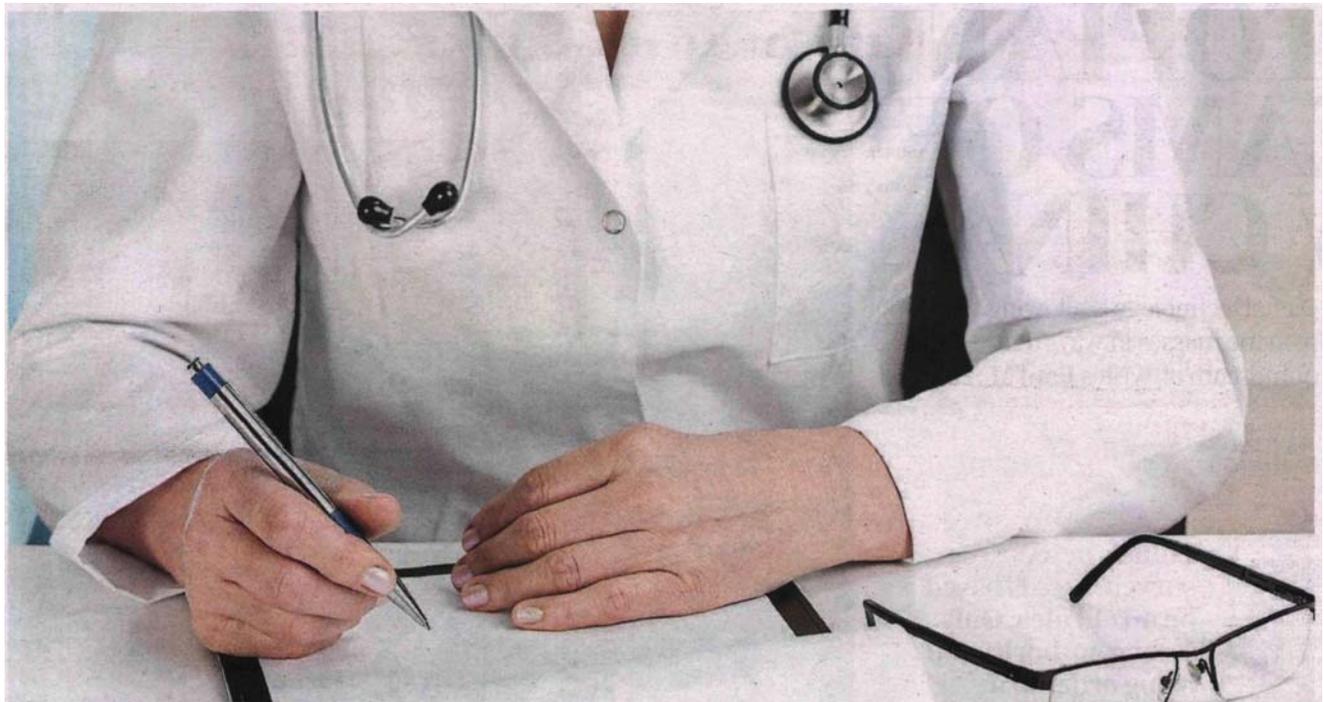


Comerford says: "Multiple GPs are prescribing it, not just specialists now, and new clinics are being opened by doctors who want to focus on medicinal cannabis as a separate part of their practice."

There are still areas of confusion. Anspec is often approached by clinicians seeking information, he says.

"We have the licences and the knowledge to supply services, including distribution, regulatory support, imports and preparation for exports, but we refer everyone to the proper authorities – pharmacists to doctors, patients to their doctors and the doctors to the TGA website.

"If everyone is aware of the boundaries that are appropriate to their profession and works within them, then this is safe and straightforward."



**Peter Comerford, below, says it is not difficult for doctors in Australia to prescribe medicinal cannabis, using a Special Access Scheme on a case-by-case basis.**

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