Accessing Medicinal Cannabis Products

Response to Statement by Therapeutic Goods Administration on Lateline story aired on 16 August 2017

The ABC's Lateline program aired a story on Wednesday, 16 August 2017 about the various regulatory roadblocks which are currently stifling lawful access to medicinal cannabis products by Australian patients. It provided a balanced and accurate picture of how the Federal, State and Territory regulatory regimes are operating in practice and, in particular, shed light on the reality being faced by those patients and their families presently attempting to navigate the complex schemes.

I wish to respond to the statement by the Therapeutic Goods Administration (**TGA**) about the Lateline story, published on its website at https://www.tga.gov.au/behind-news/responding-lateline-accessing-medicinal-cannabis-products. My response is from an informed position, having worked in the Australian healthcare system for 25 years, first as a PhD-qualified scientist in the pharmaceutical industry (in medical and regulatory affairs) and then as a legal practitioner specialising in health and life sciences, particularly in the regulation of medicines, biologicals, medical devices, cosmetics and foods.

Evidence required for approval under Category B of the Special Access Scheme

The TGA's statement suggests that the main reason for the relatively low number of approvals for access to medicinal cannabis under Category B of the Special Access Scheme (**SAS Cat B**) is the absence of clinical trial evidence establishing the safety and efficacy of such products. However, this ignores the fact that SAS Cat B approvals are granted in respect of individual patients on a case-by-case basis. It is on this very basis that a history of the successful treatment of an individual patient with a particular medicinal cannabis product – whether licit or illicit – without adverse effects should provide compelling "N of 1"-type clinical evidence sufficient to support an SAS Cat B approval for that patient.

The N of 1 evidence model is particularly relevant in the case of patients like Suli Peek, the child featured in the Lateline story. Prior to commencing treatment with an illicitly-sourced cannabis oil containing THC, Suli was experiencing life-threatening seizures – sometimes in excess of 100 per day – resulting in repeated hospitalisations and significantly diminishing her quality of life. The fact that a medicinal cannabis product – albeit illicitly-sourced - effectively reduced Suli's seizures by 90 to 95% provides compelling evidence of the efficacy of that product **in Suli**, and the lack of evidence of any untoward side effects during the two years Suli has been taking the product provides compelling evidence of its safety as a treatment for her.

What the regulators are refusing to acknowledge, in this regard, is that it is not the evidence at large which is relevant in assessing any application by Suli for individual patient access to medicinal cannabis; it is the evidence **in her** that is relevant, such as **her** prior medical history (including prior treatments she has used) and the efficacy and safety of the THC-containing medicinal cannabis product – illicit or otherwise – **she** has used.

In this regard, it is well known that the therapeutic effect of medicinal cannabis is not necessarily the same between individuals due its mechanism of action on the endocannabinoid system, meaning that randomised controlled trials are not necessarily the most appropriate evidence base for determining the safety and efficacy of medicinal cannabis treatments. Justin Sinclair, the pharmacognosist selectively quoted in the TGA's statement, discusses this issue further in his open letter to the TGA, which has been released alongside our statement.

Bureaucratic red tape is stifling access

Suli is one of the tragic cases that has motivated a talented and dedicated team of lawyers at Mills Oakley to work *pro bono* to raise issue with the level of bureaucratic red tape that is stifling access to medicinal cannabis products to patients who desperately need them.

Suli is a palliative patient who meets the definition of a Category A patient for SAS purposes, meaning that approval at the Federal level for her to access medicinal cannabis is not required.[1] At the State level, Suli meets the definition of an "eligible patient" under Queensland legislation and is, according to that legislation, therefore eligible to be prescribed an "eligible medicinal cannabis" product, which is defined under the legislation as a product containing THC **and** CBD.

However, notwithstanding the legislation, Queensland Health recently introduced a "policy" directing that medicinal cannabis products containing THC not be administered to patients under 25 years of age. This appears to be the basis upon which Suli's treating doctors are *prima facie* refusing to prescribe a THC-containing product to Suli, the very type of product she needs. This is in the face of those same treating doctors having seen first hand the profound benefit that the THC-containing product Suli has been taking for the past two years has had on seizure reduction and quality of life in Suli.

To those who may argue that Suli is being denied treatment based on the proposition that medicinal cannabis may cause harm to developing brains, I have this to say: the potential harm, including the significant brain damage, caused by the multiple seizures that Suli has suffered without medicinal cannabis, combined with the severe and debilitating side effects she has suffered from the use of conventional treatments, far outweighs any theoretical risk that medicinal cannabis may cause to her developing brain. In any event, the proposition is irrelevant in Suli's case, because a risk assessment was completed by Suli's treating neurologist, who confirmed **in writing** that there was **no suspicion of harm** arising from Suli's use of medicinal cannabis.

What is most important for Suli right now is her quality of life, something which, as her father so poignantly expressed during the Lateline story, **no one** has the right to deny her. The fact that Queensland Health has taken it upon itself to implement a "policy" which is contrary to the legislation and has effectively blocked access to patients like Suli is an indictment on the system, and is driving the use of medicinal cannabis into the black market. At some point, common sense has to prevail – we desperately need a more sensible and workable regulatory scheme that provides reasonable access to medicinal cannabis to patients who need it.

The suggestion in the TGA's response that medicinal cannabis is subject to the same level of regulation as any other schedule 8 medicines is plainly wrong. As the TGA correctly states, like schedule 8 medicines, the TGA controls the supply of medicinal cannabis products whilst the States and Territories are responsible for authorising doctors to be able to prescribe those products. However, the difference is that unlike other Schedule 8 substances, which doctors are granted a general authorisation to prescribe under the State and Territory drugs and poisons legislation, medicinal cannabis products are subject in a number of States and Territories to specifically targeted legislation requiring doctors to obtain further approvals before prescribing, approvals which effectively duplicate regulation at the Federal level and only serve to further delay access.

Facilitating access

It is encouraging that the TGA has said that it is working with States and Territories to streamline the approval processes, thereby facilitating access to medicinal cannabis in the future. However, unless this is coupled with a more sensible approach to the evidence required to support individual patient access to medicinal cannabis, patients will continue to face the unnecessary obstacles and delays that are currently driving them to look for illicit sources.

If you missed the Lateline program, we encourage you to watch the full story at http://www.abc.net.au/lateline/content/2016/s4719647.htm, or read the associated article, which can be accessed at http://www.abc.net.au/news/2017-08-16/medicinal-cannabis-red-tape-government-doctors-black-market/8813962.

Dr Teresa Nicoletti
Partner, Mills Oakley

[1] A Category A patient is defined in regulation 12A of the *Therapeutic Goods Regulations 1990* as *"a person who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment."* Medical practitioners are not required to obtain prior approval from the TGA to treat a Category A patient, but are required to submit a notification to the TGA within 28 days of the commencement of treatment.