



COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Current barriers to patient access to medicinal cannabis in Australia

WEDNESDAY, 29 JANUARY 2020

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SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Wednesday, 29 January 2020

Members in attendance: Senators Askew, Bilyk, Di Natale, Hughes, Siewert, Urquhart.

Terms of Reference for the Inquiry:

To inquire into and report on:

The current barriers to patient access to medicinal cannabis in Australia, including:

(a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access

Scheme (SAS), Authorised Prescriber Scheme and clinical trials;

(b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;

(c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;

(d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;

(e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;

(f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;

(g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;

(h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;

(i) the current status of the domestic regulated medicinal cannabis industry;

(j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;

(k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;

(l) the significant financial barriers to accessing medicinal cannabis treatment;

(m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers

and the impacts associated with that; and

(n) any related matters.

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CHAIR (Senator Siewert): I declare open this hearing of the Senate Community Affairs References Committee's inquiry into the current barriers to patient access to medicinal cannabis in Australia. We acknowledge the traditional owners of the land on which we meet and pay our respects to elders past, present and emerging.

These are public hearings, and a Hansard transcript is being made. The hearing is also being broadcast via the internet. These are formal proceedings of the Senate, and the hearing must be conducted in an orderly and respectful manner. Therefore, I would like to remind everyone that they are not permitted to disrupt or interfere with the committee's proceedings or witnesses at any point during the hearing. I also remind all witnesses that in giving evidence to the committee they are protected by parliamentary privilege. It is unlawful for anyone to threaten or disadvantage a witness on account of evidence given to a committee, and such action may be treated as a contempt of the Senate. It is also a contempt to give false or misleading evidence to the committee.

The committee prefers all evidence to be given in public, although the committee may determine or agree to a request to have evidence heard in private session. If a witness objects to answering a question, the witness should state the ground upon which the objection is taken, and the committee will determine whether it will insist on an answer, having regard to the ground on which the objection is taken. If the committee determines to insist on an answer, a witness may request that the answer be given in camera. Such a request may also be made at any other time. The committee understands that all witnesses appearing today have been provided with information regarding parliamentary privilege and the protection of witnesses and evidence. Additional copies of this information can be obtained from our secretariat.

I would like to welcome our first witness, representing United in Compassion. Thank you very much for appearing today. We have your submission. Thank you very much. I'd like to invite you to make a short opening statement. As you can see, there are a number of senators here today, with very intense interest, and I'd like to get as many questions in as possible. I invite you to make an opening statement. Thank you.

Mrs Haslam: I'd like to thank the committee for giving me the opportunity to be here today. This is a subject that has become a huge part of my life for all the wrong reasons. I feel I have a civil duty to be here and to give an insight into the plight of many Australians that usually goes unseen and unheard.

In 2014 I was invited Canberra to address MPs about the value of medicinal cannabis for people with a terminal illness like my son Dan. At the time, Dan was 24. He was suffering terribly from stage 4 bowel cancer. He had severe chemotherapy-induced nausea and vomiting, which was unrelieved by conventional pharmaceuticals, including many very expensive new-age medications, which we'd been assured by medical practitioners would be effective. But they were not. As a last resort, I encouraged Dan to try cannabis. I can never overstate the incredible difference it made to his quality of life, but the cost was enormous. We were criminals. We were buying from the black market. We didn't have a clue what we were doing. But the relief made it all worth the risk.

I was a nurse. I was married to an anti-cannabis, ex-drug-squad police officer. We had always viewed cannabis as a dangerous gateway drug. In breaking the law, the pressure was enormous, but the difference it made to Dan was impossible to ignore. I chose to educate myself and I found that, like many Australians, I had been terribly misinformed, brainwashed even, to believe that cannabis was only harmful. That was why Dan and I began to lobby for a change in attitude and a change in law. Cannabis is definitely not just about getting high. It's about getting well and about genuine patients getting very beneficial side effects for genuine relief of suffering.

Before Dan passed away in 2015, he asked me to see this through. I promised him I would, and that's why I'm here today, still advocating for patients who have so badly been let down by the current system. I feel I'm well placed to be able to draw the conclusion that the system chosen by the Australian government is failing. For many years I owned a nursing service where I had a staff of over 50 delivering care to hundreds of patients with all manner of high-support conditions including severe brain injuries, spinal injury, palliative care, children with severe physical and intellectual disabilities, and so on. And then Dan was diagnosed with a terminal disease, and these experiences cemented my deep understanding of the issues being experienced today by thousands of patients and their carers.

Back in 2014, this important issue received enormous support from the wider community, who recognised the need for compassion. But for a plethora of complex reasons the government and the medical profession, via the colleges, have made access so restrictive that the majority of patients, in ever-increasing numbers, are still, in 2020, utilising the illicit market regardless of the legislation. This fact alone is the single issue that highlights the

failure of the system, with the result that innocent patients in large numbers are criminalising themselves and putting themselves in the way of the many risks associated with accessing medicine of unknown provenance, quality and content. Yet this is an issue that so many health and political authorities, including the federal health minister and the Prime Minister, seem to disregard. These are the quiet Australians that I hope that this inquiry will give voice to.

Today you will hear from supporters of the TGA administered system who say there is not enough high-quality evidence to justify wider access; that cannabis is dangerous, toxic even; and that there are rapidly increasing numbers of approvals every month, therefore it must be a success. And while I would agree in part with some of these facts, I would disagree that these same, frequently exaggerated, claims justify a system which drives thousands more to the illicit market. There are many arguments around harm minimisation and patient centred care that would and should see a more inclusive system as highly desirable both from our health authorities view and from the patient's view.

I would ask you to consider who stands to benefit from the current system. It is certainly not the patients. This system criminalises them; disadvantages them financially; adds extensively to the burden of their disease and suffering; results in high levels of mental health torment, such as acute anxiety and depression; and creates fear of being ostracised by their doctors, of being criminally charged and of having their children removed by human services. All these things are the results of having to go it alone because they are essentially locked out of the legal route.

I have seen and heard from many of these patients who do use and will continue to use the illicit market for one simple reason: they get relief. The double standards relating to cannabis medicines, the high-level propaganda around harms and the multilayered bureaucratic system all clearly act as handbrakes by adding unnecessary cost and effort. These all combine to create a climate of discrimination and desperation for genuine patients. As a nurse and as a mother I cannot turn my back on those facts, and I unashamedly stand by Dan and others like him who are fighting to have their human rights to relieve suffering acknowledged.

Australia's beloved Olivia Newton-John is a cancer patient benefiting enormously in not only her general wellbeing but also in her battle against active tumour spread. But Olivia is one of the lucky ones; she lives in a US state where she doesn't have to break the law to get the treatment that best serves her. She's in contact with world experts in cannabinoid therapy, both in the US and Israel. Her treatment is scientifically based and current. Yet, when she comes to Australia she steps backwards to a country that fails to keep up to date and recognise research from other parts of the world.

I'd like to encourage each of you to reflect on how you would feel if it were your child who was having uncontrolled seizures whilst being filled with a dangerous cocktail of AEDs. The illicit route to cannabis that potentially manages their seizures would provide an attractive risk worth taking when many doctors are content with the dangerous status quo. Similarly, a cancer patient or chronic pain patient in the family has a far-reaching ripple effect. Seeing a loved one suffering is torment, and you will do anything to relieve the pain and restore quality of life. If it were you, your mother or your son, what would you do?

Of particular concern to you, I see, are the number of veterans who are forced to utilise the illicit market to manage PTSD. Many report their requests being denied or exhaustive battles with gaining access and with DVA funding their approved cannabinoids. It has been slow and arduous, and now we have rumours that DVA is withdrawing that funding.

CHAIR: Sorry to interrupt, but I know that senators are very keen to ask some questions.

Mrs Haslam: I'm almost finished.

CHAIR: Okay, thank you.

Mrs Haslam: We have a system that is content with making them drug addicted and then uses the same excuse to deny them access to a product prescribed in other parts of the world specifically for the care of veterans with PTSD and suicidal ideation. We should be ashamed and alarmed. I know I am.

I know that any recommendations the committee may make will likely fall on deaf ears, but that is not a reason not to make them. I don't see how we can make any change if at first we don't acknowledge the problem. I pray that this inquiry will help the government recognise the many issues and incentivise them to fix what is clearly broken. I apologise for being longwinded, but I just needed to get that out there.

CHAIR: I understand that. I'm also trying to balance. As you can see—this is for everybody who's appearing today—we have a very, very packed agenda, with lots of people taking a keen interest, so I am going to have to be pretty sharp in making sure that I meet everybody's needs. Thank you very much.

Senator BILYK: Thanks, Mrs Haslam, for your very good submission and for the written submission as well. In your submission, on page 13—I don't know if you want to look at it or not—you talk about policy access for health professionals and them not being able to access the policies. It's talking about a certain state or territory's processes; it's redacted, so we can't tell which one. But can you just talk a bit more to us about the problems with that? Also, you talk about access to MC being a postcode lottery, so could you talk about those two things and just expand on that a bit for us?

Mrs Haslam: Okay. That first point was in relation to a particular doctor in New South Wales who approached us because of the problems that he was having in trying to prescribe and finding the information about what was required prior to making that application.

Senator BILYK: So this was a doctor, not a patient.

Mrs Haslam: This was a doctor. Basically, he approached us because he felt that it was a circular system. He needed information on how to make the application. The information was not available to him, so he would make application and then he would be denied access based on policy of the state. When he asked to see the policy of the state, he was told that it was not available. When he asked why it was not available, he was told it was not a requirement for them to make it available.

The reason I put that in—it is a little historic now—is that I wanted to set the tone for what has been occurring from day one. Essentially, it was a system where doctors were expected to be able to make application for their patients, yet they tried very hard to get the information required and were kind of blocked at every turn. My understanding is that things are now a little easier, and one would hope those policies are being made available to doctors, but this is the climate which this whole system was initiated with. If a doctor can't find information on how to prescribe before he does the application then he's really just wasting his time. So there's no point in the doctor even thinking about it, because we know doctors are time poor.

The other thing about the postcode lottery is that I still believe that to be the case today, and I think that there are some people presenting later today from some of the states where it is more difficult. Why should it matter which state or territory you live in in Australia? The state or territory determines your ease of access or lack thereof. I think there are jurisdictions, such as the Northern Territory and Tasmania in particular, where the numbers are incredibly low for all manner of reasons, including lack of numbers of prescribers but also levels of bureaucracy.

Senator BILYK: Yes, you've got three Tasmanian senators at the table, and for us it's a very important issue.

Mrs Haslam: We hear a lot of complaints about Tasmania in particular.

Senator BILYK: Yes, you have to go to a specialist.

Mrs Haslam: Yes, and I think it has to come through a hospital. How does that affect rural and remote patients?

I certainly had a very distressed call over the Christmas break from a very distressed carer in north-western Tasmania whose husband was suicidal. She didn't know where to go. She didn't know what to do. But he was being denied access from even presenting at accident and emergency because he was labelled as a drug seeker.

So they're the kinds of calls that I get every day from people that are seeking help. I entered into this because I was a mother, first and foremost, but why am I here, years after my son has passed away? I still get those calls every day. If the system is working, that shouldn't be the case. They should have the help from their health professional, from their treating doctor, and the doctor shouldn't be ostracised for doing it.

Senator BILYK: How do you think we can improve the current regulatory framework that we've got? Have you got any ideas?

Mrs Haslam: I firmly believe we've chosen the wrong regulatory framework. It's so broken I think even fixing it is going to be difficult. I think we need a new system. I think we need to go back to the beginning and back to what was recommended originally by the Senate inquiry in Canberra in 2014, 2015. We need an independent regulatory body where cannabis can be treated differently to other pharmaceutical drugs. We know that there's not going to be the investment in the clinical trials that are going to be required for listing it on the ARTG. We know that cost is one of the biggest factors that's impacting patients and providing a block to access, and I don't see how that is ever going to be addressed under the current system.

Senator BILYK: What do you think we need to do in regard to making sure that doctors are more aware of the processes?

Mrs Haslam: I think there has been very negative messaging about cannabis from government from day one, from the top down. Why would doctors be interested in prescribing something that already has to go through a

special access scheme, which puts roadblocks and barriers in place because of the time required and the expertise required to do those applications? That's why we see specialist clinics popping up, which is adding another layer of cost to patients. I think the messaging has been negative from the top down from day one.

Senator BILYK: What can you tell us about the specialist clinics? I read about them in your submission, but what can you tell us about them?

Mrs Haslam: The main route this is administered is through the Special Access Scheme, which is an application process. I will admit: the process is far simpler than it was originally. Back in 2015 I got a poster made up of the flowchart of how to go through the Special Access Scheme, and it ended up being nearly a metre long. It was so ridiculous. It was demonstrated very well. I had to stand on a table to hold it up!

Senator BILYK: How long would that chart be now, four or five years after?

Mrs Haslam: Probably a lot better, because some of the state barriers have been removed from the process. But the fact is we're treating it like a medicine of last resort and as something available through the Special Access Scheme. The fact now that the numbers are going up—the government argues it's a success, because the number of approvals is going up—actually means that it's not something that should be made available through the Special Access Scheme. Even though those numbers are still relatively low, they're actually greater than what the Special Access Scheme was intended for. So in some ways the success of the Special Access Scheme is actually showing it was the wrong system in the first place.

Doctors shouldn't have to put in an application and get approval from state ethics committees to give something to their patients. Why is the government interfering in what should be the doctor-patient relationship? A doctor can prescribe opiates or benzos at the drop of a hat, yet we're putting in these extra layers, which add time, cost and burden to patients.

Senator DI NATALE: Firstly, let me just say, Mrs Haslam, thank you for your advocacy over a long period of time. I know it was born out of very difficult circumstances for you personally. Perhaps that's where I'd like to start. I know you've told this story before, but can you briefly explain to me how you first became familiar with the issue of medicinal cannabis as a result of your son Dan's diagnosis?

Mrs Haslam: It was really just a matter of last resort.

Senator DI NATALE: Perhaps if you explain the diagnosis and the symptoms he was having.

Mrs Haslam: Dan had stage IV bowel cancer. He'd been having chemotherapy continuously for four years. He had developed anticipatory nausea, where just the thought of chemotherapy would make him vomit. He was on fortnightly cycles of chemotherapy. He would start to vomit the day before chemo, he would vomit on the way to chemo, he would vomit through chemo and he would vomit on the way home. In the end, the only way we could manage him medically was to take him straight from the chemotherapy suite and have him admitted to hospital and put on a drip. He'd lay in the dark on a hospital bed with a drip for three days while he had his chemotherapy pump on, and then it would be removed and we'd go home. He wouldn't eat or drink in that time, and he would usually lose five or so kilos every fortnight. After a few days he'd start to get an appetite back and we'd try to fill him with high-calorie foods and try to get some weight back on, ready to do it again.

That was called anticipatory nausea. Nobody in Australia could help us with that. It turned out that it really mirrors something that is described in other parts of the world but not here. I was desperate. It was soul destroying. Our whole family was going through chemotherapy every fortnight. When a friend of his who was also a bowel cancer patient suggested to Dan that he try cannabis, because he used it through his treatment and it worked very well, Dan said, 'No, Mum and Dad will never allow me to do that.' But his friend rang me and I said, 'Yes, please bring it around.' My husband had been in the drug squad and he knew how to roll a joint. He rolled Dan a joint, Dan smoked a joint and he never vomited again during chemotherapy. He began to eat and drink normally. He had an appetite. He had quality of life. He didn't have to be hospitalised for three days every fortnight; he could stay at home with his young wife. It was a quality-of-life drug for him. It was just something that I could not ignore.

Senator DI NATALE: Are you still hearing cases of people—people whose situation may be different but the impact on their quality of life is just as profound—still struggling to access the drug through legal pathways?

Mrs Haslam: Absolutely. As I mentioned, one of the biggest concerns for me—I also had a son in the military—is the situation of our veterans. We know that the suicide rates are through the roof. These are our war heroes and they're struggling with PTSD. We're losing them. They're drug addicted because of their time in the military. They're prescribed opiates and benzos and they come away drug addicted. They are often discharged because of their drug addiction. A lot of them find cannabis illicitly. I've certainly dealt with veterans who have

been charged criminally for using illicit cannabis to manage something that they are now prescribed legally. They fight to get it subsidised through DVA. There are all manner of patients.

Senator DI NATALE: What's the typical patient experience? Let's use another example of somebody who is having nausea that's not responding to conventional medical treatments. What's the typical complaint you get when somebody says, 'I have to continue to access it illicitly'? Do they go to their GP and their GP is not willing to prescribe it? Or they are willing but they find it's just too difficult? Describe to me some of the problems.

Mrs Haslam: There's some of all of that. Firstly, it's difficult to find a doctor who is willing to prescribe. That's often very difficult. Many patients are turned away by their doctor. Many patients are rudely shown the door by their doctor. It could be a doctor that they've been with for many years. Some doctors actually contact us and say, 'I don't have the time; can you help this person?' or they give them our phone number and say, 'Can you point them in the direction?' It's just madness. If they find a doctor and they get an application done, a lot of them then can't afford to fill that script.

That application is being counted in the government figures. So, when the government is saying there might be 23,000 approvals, that doesn't equal 23,000 patients. By the time you have multiple prescriptions for patients who may try one product that doesn't work and another product that doesn't work and another, that's one patient with three scripts before they've even gotten started, or it's repeat prescriptions. So I think there are a lot of falsehoods in the numbers that are being presented to us.

The numbers are going up and they're going up quickly, and that's fantastic, and approvals are more quick than they used to be. But it's this many compared to this many who are using the illicit market. So the illicit market numbers are going through the roof—and, no, I can't provide you with exact numbers, but, based on conversations that I have with the green market, they are basically saying, 'We can't cope. We need help. How do we turn these people away?' These people are being turned away by their doctors or they're being driven away because of price or other factors, so they go to the black market, or the green market. They do it because they get relief, but they criminalise themselves in the process and I don't think that that's right. They're genuine patients seeking genuine relief for conditions.

My whole argument is the fact that they're doing it anyway. We need to make them as safe as possible. A more inclusive system will have them under the care of their doctor, will have them being supervised, will have them getting a product where they know what's in it. A classic example is the Lambert initiative. It looked at cannabis that was being supplied to children with epilepsy through the black market. Parents thought they were giving their children high CBD. A lot of those products had high THC in them. It's important that people know what they're giving their loved ones. Mind you, that was working for those children, so it should be a case of whatever works for the person, and that's a whole other matter.

Senator DI NATALE: The basis of your argument is that a GP should be able to prescribe this like they prescribe other drugs and they shouldn't have to go through the additional barriers and hurdles that are, clearly, limited to cannabis—obviously, the fact that it can only be prescribed through the Special Access Scheme as a drug of last resort. You're just saying: leave that decision in the hands of the doctors and make sure that people know exactly what they're getting when they're getting a prescription from a doctor for medicinal cannabis. Is that a fair summary?

Mrs Haslam: That's right. That's a normal doctor-patient relationship. Yet for some reason the government has decided that they need to interfere in that relationship. We have patients that are told that they have to go to the doctor every day for two weeks after getting their first prescription. We don't do that for other medications. Why do we single out cannabis and make cannabis different to other medications? As a doctor I would be annoyed, professionally, if I were in that position, where I was being questioned over every application that I made for every patient.

Senator ASKEW: It is a concern that doctors don't feel like they've—my question is more about the education of the doctors. Do you think that the doctors have the confidence and the educational ability and awareness of drugs like medicinal cannabis?

Mrs Haslam: No, I don't, and there's been no leadership on this at all. My own organisation has put on several international symposiums, where I've brought experts to Australia to speak to this. Most GPs or doctors generally wouldn't know an endocannabinoid system if it bit them on the backside, quite frankly. Why is it not part of the curriculum? It's not rocket science. This is going on all around the world, yet we seem to think that because we live on an island we don't have to look at what the rest of the world knows and does about this. I had the privilege of going to Israel in 2016 with Premier Mike Baird and sat with Raphael Mechoulam. There was an incredible wealth of knowledge there. It's abundant. We just have to look for it.

In our country, I think, doctors don't know what they don't know. But the bigger problem is they don't want to know what they don't know. We still have this stigma and bias around cannabis. We still see it as a dangerous gateway drug. Why wouldn't you? That's what we've been brainwashed to believe. So, unless you actually show the initiative and want to care for your patients and get yourself educated, you are probably going to remain in that group that's quite content to show your patient the door rather than help them on their journey to finding some relief.

Senator URQUHART: Mrs Haslam, is that position that you're saying doctors are taking being driven by the medical profession or is it being driven by the reluctance of government to see this as a normal type drug? What's your view on it?

Mrs Haslam: I think there's a bit of both of those. As I said, I think the messaging from high up has been negative. I think there's influence from pharmaceutical companies. I think there's a lot of vested interest, but I also think that there are a lot of personal biases on the part of doctors. It really comes down to education. There has been an education vacuum. I think we need to see more education.

Senator URQUHART: Who needs to drive that education?

Mrs Haslam: It would be lovely to see that leadership coming from the colleges and the government. I provide it in a space where no-one else is bothering. I just see this as such an important thing, and I think that the public need to be really aware of the facts. I think this is the first time we've seen medication driven by a public desire to achieve it; that's really because of nothing more than the internet. We need to make people safe. Doctors needs to get onboard or we're going to continue to see a green market that is growing and flourishing. There's no point in having legislation at all.

Senator URQUHART: Thank you.

CHAIR: Senator Hughes had some questions for you. If it's okay with you, we'll put them on notice, because we're at 10.30 now.

Mrs Haslam: Of course.

CHAIR: We will forward those to you.

Mrs Haslam: In finishing, I will leave the secretariat with a letter from Olivia Newton-John, which I received only this morning; a letter from her husband, John Easterling, who is a plant scientist; and some questions for DVA from veterans groups. If that's okay, I would like to leave those questions. I promised I would do that.

CHAIR: Is the letter a letter that Ms Newton-John wants tabled, or is it private correspondence?

Mrs Haslam: To be honest, I don't know. I just received it this morning.

CHAIR: Do you want to give it to the secretariat, and if you can let us know—

Mrs Haslam: I can find out.

CHAIR: We go through a process with tabled documents anyway, but it's important for us to know that she's happy for that to be made publicly available.

Mrs Haslam: I can send it to you electronically, if she's happy with that.

CHAIR: Fantastic. Thank you for your time today. It's very much appreciated.

GILES, Mr Andrew, National Policy Officer, Multiple Sclerosis Australia

IRELAND, Ms Carol, Chief Executive Officer and Managing Director, Epilepsy Action Australia

LUKER, Dr Tennille, Research Development Coordinator, MS Research Australia

Evidence from Ms Ireland and Dr Luker was taken via teleconference—

[10:34]

CHAIR: Welcome, Mr Giles. Because we're so pushed for time, we'll get started while we're getting our other witnesses on the line because I want to allow for as much time as possible. Mr Giles, I invite you to make a short opening statement.

Mr Giles: Sure.

CHAIR: If our other witnesses are online soon we will go to them for a short opening statement, but, while we get the others on board, we'll start asking you questions.

Mr Giles: Thanks very much. Senators, thanks for the opportunity to speak this morning. I won't give you a story about multiple sclerosis, because I know that certainly some of you on the panel are personally connected and have an understanding about the disease. I won't need to go into that. I have an email here from a person living with MS that I thought would be a good way of encapsulating an opening statement. This chap says: 'My neurologist proposed that it may be useful, but I initially said no. After two more visits, my neurologist suggested it again'—that is, medicinal cannabis. 'I took the view that it probably can't hurt to try. He then wrote to obtain relevant approvals and had a script for me with approvals a few weeks later. I first tried my local pharmacy'—this is about cost—'who charged me \$220 for a 25 ml bottle of the medicinal cannabis product. He told me that about \$100 of this was for a special security courier. That prompted me to ask around. I tried several pharmacies who couldn't or didn't stock it. Eventually I found a pharmacy who sold the same 25 ml bottle for \$115. I think they place a bulk order for multiple customers. So there are issues, including knowing how to shop around and finding who has it, and the whole idea of security couriers and their cost and who can do bulk delivery to spread this cost over their stock.'

He goes on to say, 'I was sceptical initially and tried baclofen and gabapentin'—which are more regular drugs for spasticity in MS—'but their side-effects were a problem for me. I eventually reluctantly tried the medicinal cannabis product. The results were very good. It stopped my spasticity and leg kicking completely, significantly reduced a burning pain and also improved my ability to pee, so I no longer had to get up multiple times at night. For a drug whose official literature reads like a trendy implausible story with poor data quality, my experience is it's incredibly effective across a range of MS symptoms. My guess is it's so effective for MS because it seems to calm down erratically firing nerves that would otherwise bring pain, spasticity and bladder function problems.'

Just to conclude my opening remarks, I'd say the MS community in general across Australia is putting pressure on the healthcare teams, GPs and neurologists. They are talking to each other. In the MS community it's a hot topic. Every time we post something about some change in regulations or some new information about medicinal cannabis, our Facebook and Twitter accounts go off. It's unbelievable. None of the conversations that we've been privy to at MS Australia or amongst the people I talk to are negative about medicinal cannabis. All the peer support group conversations that I've been privy to and the social media chatter are all about the positive benefits, along with frustrations to do with access and cost. The only other thing I'll add, which is in the submission, is that the first—that I'm aware of—medicinal cannabis product specifically for spasticity in multiple sclerosis is a product called Sativex. That's its brand name. It's going before the PBAC in March, so we'll wait to see the result. So there is movement on that front as well.

CHAIR: Thank you. We now have Dr Luker and Ms Ireland with us via teleconference. We got started because we're very tight on time. Dr Luker, I invite you to make a short opening statement and then, Ms Ireland, I'll come to you. Then we'll go to some questions. I was explaining to the witnesses who are here that I have to be very tight and very mean in terms of timing and cutting people off, so I apologise in advance. Dr Luker, I invite you to make a short opening statement.

Dr Luker: Sure. I want to start by saying that MS Research Australia supports access to approved, quality assured, evidence based treatment options that have been proven to be safe and effective. Our position on these are guided by a scientific, evidence based approach. It's important to note that MS is a very varied condition. Not everyone with MS responds to medications in the same way. So having more treatment options available will increase the opportunities for people with MS and their doctors to find effective therapies suited to their individual circumstances.

MS costs \$1.7 billion per year for the Australian community, and nearly 50 per cent of this cost is due to loss of productivity of people with MS and their carers. Muscle spasticity in particular can increase the reliance of people with MS on their carers and can cause decreased productivity in the community and workforce. In the case of medicinal cannabis, such as Sativex, which was brought up earlier, access to these clinically proven medications—including those released since then—will help people with MS keep active in their communities and remain in the workforce and basically decrease the loss of productivity, which will benefit the Australian economy.

I think the major thing is: there's a lack of transparency as to how to access medicinal cannabis for both the consumer and the medical practitioner. That needs to be resolved, massively. There are a lot of other access issues as well that need to be resolved to make things easier so people can actually benefit from these treatments. So that's my opening statement.

CHAIR: Thank you. Ms Ireland?

Ms Ireland: Thank you for the opportunity. For the sake of time, I won't, obviously, read out all of the recommendations that we've made in our submission. I would just like to mention a couple of things. We are very much representing the needs and views of adults and children living with epilepsy and basing the information and our recommendations on their viewpoints. I just want to summarise things that I think you will hear again and again but I just want to summarise them in very simple terms.

One of the key issues is cost. It remains an absolutely key issue. Another key issue is around doctors' willingness and ability to prescribe. In general terms, 'Doctors are still not feeling confident to prescribe,' is what the patients are telling us. There is a real issue for patients in being able to transition from artisanal to regulated product. That obviously is a concern for us, with all the criminal implications that exist there. And there is an issue around consistency in supply when they do get a regulated product.

As an organisation, our position has evolved from being extremely conservative, back in 2014 when patients first approached us, to being cautiously open-minded. We have certainly heard some good stories. Epilepsy is a neurological condition that can have an absolutely profound impact on quality of life, particularly for that 30 per cent of people who have intractable or medication-resistant epilepsy. The main reason that our clients, the patients, want to try medicinal cannabis products is to get a better result and also to avoid some of the side effects of the currently available anti-epileptic medications.

That is in absolute summary. I do have one brief case study that I'd like to tell you about, and it's somebody we're working with at the moment. He's a 17-year-old boy who's been receiving a cannabinoid product through Sydney Children's Hospital, and he's done extremely well in terms of his epilepsy and seizure control. His parents were led to believe that if there was a good outcome he would be able to continue on the cannabis product with some financial support. He has an employment goal. He's enrolled in TAFE. The problem has come where he's actually ready to transition now into adult services in the health sector and there seems to be no possibility of funding. His mother is absolutely wearing herself thin and tired and exhausted trying to raise enough money, but cost remains an absolute issue there. I'll stop there and happily take questions.

CHAIR: Thank you. Senator Hughes, I'm going to try again.

Senator HUGHES: Thank you, Senator Siewert. My apologies for before. And I apologise for not being able to be in the room. I had my eldest start high school today, so I had to stay in Sydney.

I just want to get a bit more of an understanding around what we're talking about, and I guess the previous witness would've been able to give some information around what we're talking about. Are we talking about marijuana? I heard a witness mention that her husband knew how to roll up a joint, and talking about CBD versus THC. What are we actually talking about here?

Ms Ireland: In our submission, we are certainly not talking about smoking a joint; we are talking about tinctures and oils that are prescribed for our patients. In that regard, we are concerned about consistency in cost and getting doctors to actually support the patients properly. It is the case, though, that a large number of our consumers are reporting that they are still using an artisanal product. Again, it's usually not smoking; it's usually oils and tinctures. In particular, we are talking about children with epilepsy.

Senator HUGHES: Are these the products with the THC removed?

Ms Ireland: For the most part, yes. The product that most parents are interested in is cannabidiol. We certainly would not suggest demonising THC. There may well be therapeutical reasons to give a small amount of THC in some prescriptions, and, indeed, that is available in some products. But cannabidiol is the product of most interest—the cannabinoid of most interest—for its anti-inflammatory and anticonvulsant properties.

Senator HUGHES: Do you have any issues, looking at it from the epilepsy side—which is something that I wanted to mention to the previous witness—with the Special Access Scheme? We are hearing that these products aren't going through the same sort of rigorous testing that a cancer drug or a pain medication is going through when you are looking at TGA approval and drug testing—and that's what the Special Access Scheme exists for. You've obviously got the portal now for the Special Access Scheme and, if people are approved, providers have a 40-hour window once that information is approved. Do you agree or disagree that that sort of scheme is a better pathway for access to these things that haven't gone through that rigorous testing process—that there is some monitoring of them?

Ms Ireland: I think we have a dilemma here, don't we? The Special Access Scheme, as I understand it, was intended to be used in exceptional clinical circumstances. But what has happened in terms of the consumer movement—if I can say that—is that—

Senator HUGHES: But aren't we talking about using this in a clinical sense, though? That's what I am trying to understand.

Ms Ireland: Absolutely in clinical circumstances. I used the words 'exceptional clinical circumstances', because that is what I understood that the SAS was about. I think it is actually much more widespread than that—the demand, the use and the need. We know that 30 per cent of patients with epilepsy don't respond to the currently available medications that they can get through the PBS and so on. So you've actually got a very broad group of people who are asking for the right to try it, because nothing else is working for them.

In terms of the current SAS, patients and prescribing doctors are still talking about the time-consuming challenges in understanding and navigating it. Even though there have undoubtedly been improvements, patients are still talking about that, as are the doctors, and I think we've seen the establishment of medical cannabis clinics popping up all around the country because the TGA SAS process has been difficult to navigate.

CHAIR: Mr Giles wanted to make a comment as well.

Mr Giles: I wanted to agree with those comments but also say that the MS Australia and MS Research Australia joint submission is also focused on medicinal cannabis. There is one product available for us, but we know that there are products being prescribed by neurologists that are coming in from overseas. We of course know that people in the MS community use marijuana that they buy illegally—and we would say: please don't smoke, because smoking is very bad for MS in any case—although people in the MS community are unlikely to talk to us much about that. Our commentary is focused on medicinal cannabis products that are available here or that come here from overseas via the access schemes.

CHAIR: Senator Di Natale?

Senator DI NATALE: Firstly, let me start with you, Mr Giles. You're, ironically, in the more fortunate position, in that the members your organisation represents, the patients, have actually got access to a drug that is registered on the ARTG, Sativex, and many others don't have access to that medication. I want to ask you specifically: what is the main barrier to somebody who may benefit from getting it, and it's been recommended, potentially by a neurologist?

Mr Giles: At the moment it is cost. It is expensive. I tried to pepper the submission with commentary about cost. There is also a bit of an anomaly—

Senator DI NATALE: Can I ask you about cost? Your earlier example was that the cost ranges from, I think, \$115 to \$230—

Mr Giles: That wasn't Sativex. That was something else.

Senator DI NATALE: What would the average cost per year to a patient be?

Mr Giles: My understanding is that on average—because pharmacists can charge anything, as we know, if it's not on the PBS—it's about \$700 to \$800 for a month's supply.

Senator DI NATALE: For one month's supply?

Mr Giles: Yes. That varies.

Senator DI NATALE: Hence you're eagerly anticipating the PBAC process to see whether it will be subsidised?

Mr Giles: Yes, we are.

Senator DI NATALE: The second issue, beyond cost?

Mr Giles: I think the other thing is frustration. The story I told at the beginning was of a neurologist who suggested it to somebody who wasn't so keen, which is a little bit unusual in a sense. There is a frustration in the

community when people go to their GP or to their neurologist. They get to see their neurologist for 10 minutes once a year usually, and it's usually about more serious disease-modifying therapies—industrial-strength medication that they're on to try to help their immune system. There's frustration with the lack of knowledge about how this might help them, because, as I said, the MS community talk to each other. There's a lot of information out there. It's not going to cure your MS and it's certainly not a disease-modifying therapy, as far as I know, but it does seem to give people, broadly, a lot of relief—a good night's sleep. That's just amazing for people. That guy who doesn't have to get up—

Senator BILYK: It improves your quality of life, Mr Giles?

Mr Giles: It's incredible. Not having to get up at night 10 times to pee. These can, for a lot of us, seem to be such small things, but for people who have been living with MS for years to have one thing—and MS changes for people. Symptoms change, and often the symptoms include peculiar burning feelings and are hard to describe. People want relief from any of the range of symptoms. Sixty to 70 per cent of people with MS are on these industrial-strength, disease-modifying therapies. They're used to dealing with side effects; they're used to having to modify their life. Think about pregnancy; think about career and all of that. If they can get some relief from symptoms with something that, in their perception, isn't toxic in the way that the other medicines are, which they go to hospital to have infusions for, like chemotherapy and like drugs, they are very keen for them. I think that gives you an indication of the feeling of the MS community and the positive disposition to this and the stories that are going around. As you can hear from Tennille and myself, our organisations are conservative. We do want the evidence. We do want the research. We do want the clinical trials. But in the meantime we've got this overwhelming push from the MS community saying, 'Hey, advocate on our behalf because we want more access and we want the drugs that we can get access to—the medicinal cannabis products—to be cheaper and more affordable so that we can try them.'

Senator DI NATALE: Do you have a sense of how many people would be accessing it illegally?

Mr Giles: No. Our best estimate is that there are 26½ thousand people with MS in Australia.. I would say half of that community have tried something. The MS community are a bit like the rest of us. There are a lot of very conservative people in the MS community. The MS community are very risk averse. If they're on some medication for a symptom or a disease-modifying therapy, they're often reluctant to change, even if there's some published evidence about a benefit. They're very risk averse. But there's pressure from family, pressure from others in the community and, I don't know, just feeling tired and sick of the symptoms and being willing to give it a go, particularly if they perceive that there isn't a high risk of having an adverse side effect, because they're used to those with the other drugs they're taking.

Senator DI NATALE: Ms Ireland, you estimate that 80 per cent of your clients are accessing medicinal cannabis through illicit markets. How did you come to that figure?

Ms Ireland: It's an estimate, obviously, and it's based on the inquiries that people make of us. We have been at the forefront of trying to develop programs and support for people wanting to access medicinal cannabis. We've not been hiding that—we've been talking to them about it, and they feel confident to talk to us. We get calls every single day from people who are making inquiries, and the majority, by far, are indicating that they're using an illicit product. They talk to us about their concerns around things like drug-to-drug interaction and often about how to try to navigate the legal process.

On the question you asked before about cost, our clients, in a survey we just did in December, are still reporting that, when they do go through their general practitioner, neurologist or epileptologist, there are predicted costs of up to \$1,300 per month. That is what one person quoted. Another person quoted that one CBD bottle per week currently costs \$370. They're the kinds of costs that we're facing for epilepsy. Usually, with a child, epilepsy is treated by a medicine, including medicinal cannabis, by weight, and children are needing far too much for their families are able to provide.

Senator DI NATALE: We've heard that there are a range of barriers—and we'll get to this later on in the program in terms of exploring what each of those are—and clearly there are a number of factors feeding in here. Given that medicinal cannabis is such a unique product in terms of sponsorship through conventional medical pathways, it's very difficult to see pharmaceutical companies providing the sponsorship of particular drugs through that pathway. What do you think about the notion of an independent regulator that treats this as a specific drug? Obviously there's a huge demand for it from within both of your communities. Are you supportive of the notion of an independent regulator that says that if a patient goes to see a doctor they should be able to get access to this drug in the same way that people in other countries can? I put that to all of you.

Ms Ireland: I spoke at the 2014 Senate inquiry and strongly supported the establishment of a regulator. My view hasn't changed. I think there has been progress and lots of effort to make the existing system work. There has been improvement, but we still overwhelmingly hear about the barriers and the difficulties. I think we're trying to force a square peg into a round hole.

Mr Giles: From MS Australia's point of view, I would say that if in setting up the independent regulator it speeds up access but still ensures that there are safe, affordable products available to people in the MS community then, yes, we'd be up for it.

Dr Luker: MS Research Australia completely agrees with both MS Australia and Epilepsy Action. As long as it speeds everything, it's still clinically proven and there is quality assurance, then I completely agree.

Senator URQUHART: One of the things that we heard this morning but that I think we already knew is that there seems to be a reluctance from the GP world or the treating doctor world to actually prescribe this as a drug generally rather than a drug of last resort. Can you talk to me about what the barriers to that are? Is that an educative process that we need to undertake or is it more?

Mr Giles: I'll have a go at that first. We struggle with educating GPs about multiple sclerosis, let alone medicinal cannabis. From an MS point of view, there are 26½ thousand people with MS in Australia at the moment. I don't know how many tens of thousands of GPs there are, but not every GP is ever going to see someone with MS, so recognising the symptoms, getting a person diagnosed and then thinking about treating some of those symptoms through medicinal cannabis is a process of education. Of course, we'd love to see royal colleges and training programs on this so that cannabis becomes a normal part of a range of things that people are prescribing. But the pressure is on, because we have talked about the clinics that are emerging that are offering online or over-the-phone consultations that will get people through the access scheme. Eventually that pressure will force an expansion of knowledge throughout the GP community anyway.

We are up for anything that helps educate GPs about cannabis. The pressure is already on, so I think that the system will just have to catch up in any case. Anything, like the primary health networks, can help. There is a lot of information out there. The TGA website is pretty good, so there is a fair bit of information out there, but it is about understanding the symptoms and then matching it to that person, and GPs are under a lot of pressure and are time poor.

Ms Ireland: I would like to pick up on that last point you made that GPs and other doctors are time poor. It is how we deliver education that is going to be critical here. In the absence of a government-led medical education program, there have been a range of individuals and entities that have tried to fill the gap. There have been a range of seminars, conferences, workshops and so on. It is perhaps thinking about how we need to deliver education. GPs are more likely to watch something, if I might say—a short, sharp video that can give them some very practical information. They are not going to read through websites at great length. Some of the patients are still telling us that their doctors just 'shut them down'. 'They're just unwilling to talk about it' and 'They're deadset against it' are some of the comments that we have got. It is absolutely clear that general practitioners need better information and more education so they can feel confident in their ability to prescribe and to titrate the cannabis.

Senator URQUHART: Following on from that, is it more an issue about the time poorness of GPs or is it also a reluctance to get involved in medicinal cannabis because of where it sits in society and government at the moment? Is that an issue as well?

Mr Giles: The range of GP attitudes is as wide as our society generally. I think you have hit the nail on the head there, though. Some people in the MS community tell us stories about their GP shutting them down and yet others have their GPs and neurologists encouraging them to try it. I think—and I think Lucy talked about this earlier—there is still a stigma; there is still an idea that cannabis is something wacky. We have had all sorts of things in the MS community over the years that are purported to cure or help with the symptoms of MS. I think cannabis is still a little bit in that realm. Clearly the research says the jury is out on whether it helps people with pain in MS, but, as far as we are concerned, it is now a mainstream option. It is not something that is out of left field anymore. We would like that time speeded up so that the stigma is removed and it becomes a viable option.

Ms Ireland: I would agree with the comments that have been made, but I would say that there have been surveys done of GPs' attitudes. The Lambert initiative at Sydney university has conducted some surveys, and the majority of GPs actually do want to know more and do want to be able to prescribe, but they are lacking the knowledge.

Senator URQUHART: What was the name of that survey?

Ms Ireland: It was a survey done by the Lambert initiative at Sydney university on the attitudes of general practitioners.

CHAIR: Senator Bilyk, I am told you have a quick question.

Senator BILYK: Thank you. In regard to the last couple of comments and questions from Senator Urquhart, I think the critical issue here is that it is medicinal cannabis—

Mr Giles: Correct.

Senator BILYK: and that is the piece we need to push. That is a statement, not a question! I do want to ask very quickly, because I know we are quite time poor ourselves: I don't know about these clinics that people are talking about except from people's submissions, so can you very quickly give us a two-minute rundown of what these clinics do, who runs them and how they work?

Mr Giles: Sure. I have had contact with a couple of them. I think they have contacted us wanting us to promote them through our networks, which we have been reluctant to do because it seems like free advertising from our point of view. They seem to encourage people to call up. They will give a \$200 or \$300 phone consultation or online you can put some details in. You have to register to get a lot of information. I have been a secret shopper and registered and spoken to some of the people—

Senator BILYK: You just blew that cover!

Mr Giles: It's not secret anymore. They will take a person who they feel, following their consultation, needs a medicinal cannabis product through the Special Access Scheme as fast as they possibly can. The two of them that I've been in touch with want a referral, or at least contact with the patient's existing GP, so there is a bit of a quality assurance barrier there. I've mentioned three that I'm aware of, but I'm sure there are heaps more across the country, and they are specifically set up for access to medicinal cannabis products.

Senator BILYK: Are they doctors or are they lay people?

Mr Giles: They're doctors—well, as far as I can tell they are doctors.

Ms Ireland: They certainly are. If you would like me to provide a list of the clinics, I can certainly do that—

Senator BILYK: That would be great.

Ms Ireland: They are doctors. They're typically general practitioners. They do typically use telehealth but do some face-to-face consultation. Some charge a fee; some don't. Some of the fees are very high; some are not as high. They do try to liaise with the treating doctors. It's only if the treating doctors aren't working in collaboration that they will actually see the patient independently. There are quite a lot of them now. I have presented several years in a row at the hemp expos at the medicinal cannabis symposium held there. Several years ago there was one and this last year, in 2019, there must've been seven or eight clinics that were there representing and promoting themselves to the patients, to consumers.

CHAIR: Thank you. I'm so sorry I have to wind this up. We want to keep hearing from every single witness. I know that's going to happen all day. I'll say this to all our witnesses that are here: if we don't get through everything you want to tell us, and you think that we should've asked, please feel free to send us further correspondence, a supplementary submission or more information. We will very happily receive that. Thank you very much to our witnesses for your time today. You gave us some very valuable information, so thank you.

NICOLETTI, Dr Teresa, Partner, Mills Oakley; Director, Medical Cannabis Council; and Member, Australian Lawyers Alliance

[11:08]

CHAIR: Welcome. Thank you very much for coming. Do you have any comments to make on the capacity in which you appear?

Dr Nicoletti: I'm a partner at Mills Oakley and I'm representing the interests of my industry clients and patient clients as a partner of that law firm. I am also a director of the Medical Cannabis Council and am representing the interest of more than 120 members, which include industry patients, doctors, nurses, patients and patient advocates.

CHAIR: Thank you very much. I invite you to make a short opening statement. I know that you want to cover a range of issues.

Dr Nicoletti: I have shortened my opening statement because I'd like to devote the time to question time. Essentially, what I've tried to do is distil a lot of the information that is relevant to this inquiry in the Mills Oakley submission and the submission from the Medical Cannabis Council. I believe a lot of the information that I would have covered here today is in that submission. I endorse both of those submissions. I am very grateful for the opportunity to have made those submissions and to appear before the committee. I don't want to take any more time on opening statements. I'd like to just defer to you for questions.

CHAIR: Okay. Thank you. Your submissions are comprehensive.

Senator URQUHART: Thank you very much, Dr Nicoletti. I just want to go to the current regulatory framework to access medicinal cannabis. From what I understand, in your submission you talk about that being inadequate. Can you just go through the steps of why that is the case from your point of view.

Dr Nicoletti: The first subject I'd like to talk about is the access schemes. Doctors are required to apply for access under either the Special Access Scheme or the authorised prescriber scheme. The issue with those schemes is that they were never really intended for the suite of products called medicinal cannabis products. They comprise many different products containing very different compositions of cannabinoids, terpenes, flavonoids and other compounds. So it's not one product that you can try that may assist a patient. Feedback that we have received from both doctors and patients is that they are frustrated by the amount of time it takes to prepare an application to submit to the TGA. It requires them to provide a clinical justification for why they have chosen that particular therapy and also to explain to the TGA why conventional treatments haven't worked. Then the TGA evaluate that application and provide an approval. I appreciate that the TGA have done what they can in fast-tracking approvals. In their submission I believe they talk about the turnaround of around 30 hours. But that disregards the time and effort required by a doctor to actually prepare a submission in the first place.

With medicinal cannabis, if you submit an application for one product and that product is ineffective, which is quite often the case when you are trying to work out a treatment for a particular medical condition, you have to submit another application and explain why that treatment was ineffective—

Senator URQUHART: And do it all over again?

Dr Nicoletti: Yes. This can be as simple as starting with, say, a 20:1 CBD product and finding out that, instead, you need a 15:1 product or you need a higher dose or you need an oil instead of a capsule. Each of those are separate and distinct goods which require a separate application. In relation to how the scheme was originally introduced, it was intended to be more applicable to conventional medicines where you have a synthetic mechanism that has a known pharmacological action and a single molecule that has a well-defined safety net because it's profiled and tends to be approved overseas but may not be approved in Australia. The scheme works well for those types of drugs. I don't think it works well for medicinal cannabis.

How can that be addressed? You could create a modified scheme that would, in my view, allow a doctor to get an approval for medicinal cannabis. It would be like an authorisation that would allow that doctor to prescribe medicinal cannabis.

Senator URQUHART: And then vary that accordingly—

Dr Nicoletti: Correct.

Senator URQUHART: without going back all the time—

Dr Nicoletti: Yes, without having to go back for more applications. I note that in the Department of Health's submission they say that ultimately the decision about the treatment is the doctor's. So I do have to ask the question: why do we have to go through this onerous application process? Why can't the doctor—one who is

properly educated, I must say—make the decision that they want to try cannabis in their patient and maybe submit a notification to the TGA saying, 'I am going to try this product in this patient'? If they decide to change, a notification form is a much easier thing to complete than having to put in a comprehensive submission with a clinical justification. That is the major issue that I have with the scheme right now.

There is also an issue around the inability to obtain reimbursement for medicinal cannabis. That's because it is an unapproved product. It is not a product which is registered on the Australian Register of Therapeutic Goods, which is a prerequisite before you can even apply for PBS listing. You can apply while an application is under evaluation, but you cannot get a product PBS listed if it is not a registered medicine. So either we would have to change the legislation to accommodate this type of product or we would have to look at other reimbursement schemes like Medicare funding or treating medicinal cannabis like it's a service, which includes subsidisation of a prescription, or looking at possibilities for private health insurance to accommodate these types of products.

I don't know the level of comfort of insurers at the moment even contemplating subsidising medicinal cannabis treatments, but one of the issues there is talking about indemnity. It's essentially an unapproved product, so what sort of indemnity issues arise both for the doctor and for the insurer considering the subsidisation. Ultimately, though, I think those issues can be addressed through patients completing indemnity forms and also signing informed consent forms, which puts it more into the control of the doctor and the patient. My view is—and this is more on a personal level than a professional level—that the relationship between doctor and patient is paramount. A doctor, particularly a general practitioner who has known a patient for a long time, will know what's in the best interests of their patients, and I do not believe that a GP will administer a medicinal cannabis product to a patient if they don't believe it's in their best interests.

Senator URQUHART: Okay. Can you talk to me about the key issues in relation to state and territory regulations, and the problems that they cause?

Dr Nicoletti: I think it is less so than it was 12 to 18 months ago.

Senator URQUHART: Why is that? What's changed?

Dr Nicoletti: The streamlining has had a major positive effect on removing a lot of that state layer of regulation. We still do hear some stories about state intervention, but not to the level of intervention that there was 12 to 18 months ago. I applaud the government for taking the steps needed to remove that state layer of regulation.

I do believe that any future iterations of the scheme need to ensure that there is no intervention by the states. I believe that at the moment Tasmania has not taken up the streamlined process. Patients in Tasmania are, therefore, affected. There's also this expectation that you can only be prescribed a product by a doctor in the same state you reside in, and so that is putting Tasmanian patients at a disadvantage.

Senator Bilyk interjecting—

Dr Nicoletti: Yes. There are other barriers there.

Senator BILYK: Apparently our GPs are less asked than GPs in the rest of Australia. That's how I read that, but that's my sarcasm coming out. Sorry, Dr Nicoletti.

Dr Nicoletti: That's all right.

Senator URQUHART: All right; I'm happy to leave it there at the moment and give someone else a go.

Senator DI NATALE: Firstly, let me congratulate you on your very thorough submission, Dr Nicoletti; it's excellent.

Dr Nicoletti: Thank you, Senator.

Senator DI NATALE: And given you're an expert on the regulation of therapeutic products, I want to explore that bit more. Also, thank you for clarifying that when we talk about 'medicinal cannabis' we're talking about a range of different products, in the same way as when we say 'antibiotics' we don't mean one thing, we mean lots of different things. Let me ask you a question about that for people who might not know. As you say, most medicinal cannabis products—there's only one as far as I know—aren't registered on the Register of Therapeutic Goods. So they're unregistered drugs, and that's why we need to go through this convoluted Special Access Scheme, which is designed for drugs that aren't approved in Australia. What is the barrier to these substances actually becoming approved as therapeutic products? Why aren't they registered?

Dr Nicoletti: At the moment all medicinal cannabis products, except cannabidiol, in greater than 98 per cent purity are schedule 8 medicines. CBD in greater than 98 per cent purity is schedule 4. By definition they're all prescription medicines; they can only be provided under a doctor's prescription. And in order to be registered in the ARTG you are required to submit a comprehensive dossier of quality, safety and efficacy data that complies

with the requirements for a prescription medicine. And I would say that for probably all companies that are currently supplying medicinal cannabis products the cost prohibition on generating the data required to support a registration is too prohibitive. We're talking about tens of millions of dollars in investment.

Senator DI NATALE: Let's unpack that a bit more, because there's a lot of technical language in that. Schedule 8 is usually about drugs that might have psychoactive properties, drugs of dependence—

Dr Nicoletti: Controlled drugs—yes.

Senator DI NATALE: and so on. Because a lot of medicinal cannabis products have THC in them, they're basically classified as schedule 8 drugs.

Dr Nicoletti: Correct.

Senator DI NATALE: To have a schedule 8 drug listed and approved you need to provide a very comprehensive evidence base, and what you're saying is that usually that's the domain of big pharmaceutical companies—

Dr Nicoletti: Correct.

Senator DI NATALE: and that many of the companies involved in medicinal cannabis just don't have the ability to generate that data.

Dr Nicoletti: Correct.

Senator DI NATALE: Schedule 4—the more garden-variety drugs, if we can call them that—don't have the potential for addiction. You're saying the drugs with very low THC or less than two per cent are under schedule 4, but schedule 4 still has prescription drugs.

Dr Nicoletti: Yes. But the point I'll make is that any CBD-rich products that have low THC but don't fit into 98 per cent purity are actually schedule 8 drugs, so they're also controlled drugs. At the very least, I think the scheme needs to look at how we are regulating these products. One of the major barriers to facilitating the scheme is the scheduling of these products, and that is a decision made by the secretary. Even if we produced legislation that addressed regulatory issues per se, you would still need to deal with the scheduling status of these substances.

Senator DI NATALE: Yes. Effectively, we've got this dilemma, if you like. We've got a range of drugs—some of which we've got very good evidence on but for some it is anecdotal—although we're now getting a lot of pressure from members of the community who have experienced a significant benefit from some of these drugs, which they've been able to access either illicitly or through the Special Access Scheme, but the Special Access Scheme treats this drug very differently to other potentially much more dangerous drugs.

The example I'll give is that, as a GP, I could prescribe somebody an opiate, like Panadeine Forte or Endone, which, if taken in large quantities, would kill them because opiates in overdose have the potential to be fatal. But, as a GP, I can't prescribe a medicinal cannabis product in the same way, despite the fact that it has almost no overdose potential. So we've got a scheme that is unable to deal with medicinal cannabis, because of some of the inherent problems with the companies that are putting forward these applications, and we've got doctors who are hamstrung, in terms of the way they can prescribe it.

I'll come back to the question I asked earlier witnesses. These are inherent in the system we're trying to administer. Given those barriers and given that they're unlikely to change anytime soon, is the only way to ensure that a doctor's able to prescribe this drug—which is safer than many of the other drugs they can prescribe already—to create an independent regulatory pathway for medicinal cannabis rather than try to tinker with an existing system that, by design, is unable to cope with the regulation of medicinal cannabis in the same way as other drugs?

Dr Nicoletti: Quite honestly, I think changes could be made to the present scheme, but the question I ask is: why would you try and adapt a scheme that has, for the last 30 or 40 years, been focused on conventional medicines and try and adapt that scheme to fit what is a very different group of medicines? I don't understand why there should be any resistance to a separate regulator to deal with this type of product.

Senator DI NATALE: So your view is that we could make changes to the existing system but that might be difficult, given that it's not designed to deal with the issues around medicinal cannabis. I don't want to put words in your mouth. But it would just be easier to have an independent regulator for medicinal cannabis in the same way as many other countries have.

Dr Nicoletti: I think so. I hesitate because I think of all the issues that would need to be taken into account, such as scheduling, such as cost, such as the regulatory 'approval' process. If I had my way, I would just sit down and set up a separate scheme and say, 'Okay, these are the things we need to do and this is how we will address them.'

Senator DI NATALE: In terms of the state issues, you've addressed those. Do you think there are any states that stand out in terms of the problems that exist there? Do you think the Tasmanian example is a good one?

Dr Nicoletti: Tasmania. If you'd asked me 18 months ago, I wouldn't have shut up, quite honestly, but a lot of the issues that were prominent 18 months ago have been addressed. But I have to say: there are a lot of people that did a lot of very strong advocacy 18 months ago to effect those changes. It was quite a frustrating scheme to work with back then. There are still frustrations, but the removal of the state layer has appeased some of those frustrations.

Senator DI NATALE: This might be a question more relevant to the industry groups—and we'll be hearing from those later—but do you think these barriers are an obstacle to us being able to develop a medicinal cannabis industry here in Australia?

Dr Nicoletti: I can answer that. I represent a number of industry players. One of my clients has spent \$35 million investing in the capital needed to establish what I call 'the Fort Knox facility' so that they can cultivate, produce and manufacture medicinal cannabis for supply. The fact that we only have two companies at the moment, since legalisation in 2016, that are actually supplying the domestic market will give you some sense that the barriers to being able to cultivate, produce, manufacture and supply are quite onerous, as well.

Senator DI NATALE: So we're really talking about a separate set of barriers now; we're talking about the production of the drug rather than access to the drug.

Dr Nicoletti: Yes.

Senator DI NATALE: What are some of the of those barriers you see with regard to, as you said, the Fort Knox facility?

Dr Nicoletti: The cost of setting up secure facilities for medicinal cannabis and whether they are even necessary for CBD products that are non-psychoactive.

Senator DI NATALE: If you're growing a strain that has almost no THC—so it doesn't get you high, just to put that in generic terms—you still need to have those security arrangements?

Dr Nicoletti: Yes. I can give you an example. A company that has a hemp licence can grow industrial hemp, broadacre. I have a client that did exactly this. If you grow that hemp strain as an industrial crop then you can grow it broadacre. You may need some security fencing, but it's just two- or three-metre-high fencing to comply with local requirements. If that same crop is used for medicinal purposes, you can spend \$10 million to \$20 million constructing a secure facility that regulates that product as a medicinal cannabis product. And that is a real-life scenario; it's not something that I'm just putting out there.

Senator ASKEW: I've got a quick question about the current legislation around the use of medicinal cannabis and cannabis in general: are you aware of many clients or patients that have been charged or have had legislation used against them with regard to use?

Dr Nicoletti: Criminally charged?

Senator ASKEW: Yes, 'criminal' is the word I was looking for.

Dr Nicoletti: Yes. I'm not sure if Mr Barns is here. He would be the better person to talk about the criminal law aspects.

Senator ASKEW: I don't think he is on the line.

CHAIR: No. We'll make sure we follow that up.

Senator ASKEW: What legislation changes do you see as necessary to relax the access to medicinal cannabis? Would that relaxing of legislation see an increase in the use of recreational cannabis and that sort of thing?

Dr Nicoletti: No. Our scheme doesn't allow recreational cannabis at the moment, and the legislation prohibits it. I think the relaxation to the scheme would be the actual patient access schemes—looking at those and how to operate those. On the industrial side, one of the major barriers is the gross under-resourcing of the Office of Drug Control. They're just overburdened with applications and are incapable of managing those applications in a timely manner. We're looking at licences taking two years to grant. In one case that I'm aware of it was more than two years. That really needs to be addressed so that the domestic industry can get up and running. Once the domestic industry gets up and running, leaving aside reimbursement issues, there will be increased supply, and natural market competition will set in and start to at least push the price down.

Senator ASKEW: That makes sense. My final question relates to the one from Senator Di Natale. You were talking about the growth, and there was your example of the industrial-hemp side of things—the ability to grow in broadacre. How does that relate comparatively to opiate plantings?

Dr Nicoletti: These are non-psychotropic drugs. As I understand it, the opioid drugs that are being grown need to be transformed first, before they have the illicit effect. I think that if you actually chewed the opiate plant it would probably kill you from toxicity. The therapeutic value comes once it's actually produced. There are different issues at play here. The hemp plant itself is non-psychotropic. If you take that and chew it, you're not going to get high.

CHAIR: Senator Bilyk has a short clarification, and Senator Di Natale has a question to put on notice.

Senator BILYK: I just want to clarify this. Is an authorised prescriber someone who has gone through an ethics committee at the college or whatever?

Dr Nicoletti: Yes.

Senator BILYK: Can a general practitioner be a prescriber if the state legislation allows it?

Dr Nicoletti: A general practitioner can apply to be an authorised prescriber if they get endorsement from a specialist college—the Royal Australian College of GPs, for example.

Senator BILYK: So, if you want to prescribe a category B drug, you would need to be an authorised prescriber?

Dr Nicoletti: No. You can apply through the Special Access Scheme.

Senator BILYK: Okay. Through—

Dr Nicoletti: Category B.

Senator BILYK: Who makes that determination?

Dr Nicoletti: The TGA.

Senator BILYK: Thank you. So there are basically two different ways you can become a prescriber?

Dr Nicoletti: Correct.

Senator BILYK: Thanks.

CHAIR: Senator Di Natale, do you want to put your question on notice, unless there will be a short answer?

Senator DI NATALE: It might be short. You raised issues around driving and medicinal cannabis. Could you summarise those?

Dr Nicoletti: Yes. The issue that we have at the moment—I will talk to New South Wales because I reside in New South Wales and that's the area I've looked at—is that, interestingly, in our Road Transport Act are provisions that make it a strict-liability offence to have a substance detected in your blood, and one of the substances in the Road Transport Act is tetrahydrocannabinol—that is, THC. Even if you have a medical prescription for medicinal cannabis, if you're at a roadside and you have a drug test and THC is detected, it's an immediate offence. The first offence costs \$2,200, I think, and every repeated offence costs \$3,300, or even more if you have repeat offences. So the legislation has not actually kept in step with the changes that have happened. There is, for example, a carve-out in the same legislation for morphine. It is an offence to have morphine detected in your system, but, if you can demonstrate to a court's satisfaction that you have a medical prescription for morphine, that is a defence to prosecution. The driving laws in every state need to be amended as well. Patients who have a prescription may not want to fill it, because they have a job in which they have to drive every day and they would be at risk of prosecution for doing something which they took steps to do lawfully.

Senator DI NATALE: Thank you.

CHAIR: Thank you very much for your time today. It was very productive and very useful.

Dr Nicoletti: Thank you.

BALDERSTONE, Mr Michael, President, Nimbin HEMP Embassy

CLEAVER, Ms Lyn, Private capacity

Evidence from Ms Cleaver was taken via teleconference—

[11:34]

CHAIR: Good morning. Thank you for coming. First off, I'm going to invite you both to make opening statements, and then we will have a few questions, if that's okay with you. Ms Cleaver, do you want to go first?

Ms Cleaver: Sure, I can go first. I am just a mum to three wonderful sons. I've got a really short statement that I'd like to read out, if that's okay.

CHAIR: Yes.

Ms Cleaver: My eldest son, Jeremy, is 28 years old. He contracted suspected acute viral encephalitis in January 1998. He was six years old. Jeremy has been diagnosed with a brain injury and severe refractory epilepsy. Since 1998 Jeremy has endured over 10,000 generalised tonic-clonic seizures. He is not a brain surgery candidate, and he was implanted at age 11 with a vagus nerve stimulator in an effort to control his relentless seizures. He has never enjoyed complete seizure control. His longest tonic-clonic-seizure-free break was just 27 days, and that was after we started cannabis. We commenced cannabis therapy in mid-2014. Initially we purchased his medicine locally until supply suddenly ceased. We had already started weaning him from his anticonvulsants. We had no choice. There was nothing else for his neurologist to prescribe. The only option we had was strong sedatives to control the side effects from his anticonvulsants, not to control seizures.

We started cultivating Jeremy's cannabis ourselves. We told his specialist, his GP, our Premier, our police minister and our health minister. We also informed Tasmania Police of our action. We have begged everyone who makes legislation to protect us and others like us. We have lived every single day since 2014 in fear that his medicine will be confiscated. I would like to say to you all that, at the end of the day, it comes down to this: do you want people, patients, to continue breaking the law? I can assure you that this situation will not change until you implement legislation that actually benefits patients. Just as we do, thousands of Australians act illegally because our health or the health of our loved ones will always trump an unjust law. Thank you.

CHAIR: Thank you. Mr Balderstone?

Mr Balderstone: The HEMP Embassy in Nimbin has been a group for 30 years, lobbying to change the law but also trying to help cannabis users. I have trouble separating medical cannabis from recreational cannabis. My understanding is that it's a medicinal herb—it has a medicinal effect—and I'm not quite sure where people draw that line. I made a few notes of things that might be of interest to you. I know of several groups in northern New South Wales who are currently probably getting a thousand people a week accessing or coming to try medical cannabis, so I reckon the figure that's being bandied around of 100,000 medical cannabis users is seriously conservative.

I hope people realise that unless you heat cannabis you don't get stoned. Unless you cook it or light a joint you don't get stoned. It's the same with high THC. If you do a cold extract of high-THC medicine, you don't get stoned. It's an important part of getting medicine. People being treating for cancer need to get a lot into their body. They can't possibly get stoned. That's an important thing for people to understand.

Saliva testing is stopping a massive percentage of people actually trying it. I can give you my own example. I've been pretty much a daily cannabis user for nearly 50 years. I used to be a shocking migraine sufferer. I would call it PTSD. I got sent to boarding school when I was young. I think a lot of people who like cannabis are treating different forms of PTSD, often from childhood. Saliva testing is a huge issue. I got busted last year and I pleaded not guilty and tried to challenge it in court, which means that they give you a report on your saliva. You're allowed to have 10 nanograms. Anything above that you get charged with. My reading was 1,250. It sounds ridiculous. It's like having not 0.5 alcohol but 5.0. The policeman in court said that I didn't appear impaired. That's because I am a regular user, and it stays in your body for a long time.

One of the things that causes a problem is that, because cannabis stays in your system for, say, a month, or two months in my case—most other drugs are out of your system in a couple of days—it has distorted a lot of figures. I think John Howard was misled by that with his link to 'cannabis psychosis'. People who go to mental health institutions all get their blood tested. They are often polydrug users, and heaps of people come up with cannabis. I remember a Victorian hospital report that said that 10 per cent of beds in Victorian hospitals were due to cannabis. I contacted them and they said, 'We test everyone who comes into hospital and 10 per cent had cannabis in their system.' That's a total distortion. It's an important thing for people to understand.

We've all been really frustrated for 40 or 50 years lobbying and saying that this is our choice of medicine. Finally, people agree that it is a medicine, but most of us are still hunted like ordinary criminals. That is a really sad thing for me. I think allowing people to grow their own medicine would be massive. All the 'official' medicine is grown indoors, in labs, and nothing is grown out in the sun and it is probably not even organic. I am not questioning the quality of the legal medicine, but it is a fact that none of it is grown outdoors. From my experience, we often find much better results for people with organic, outdoor grown cannabis.

Cannabis is super safe. It is not for everybody, I would agree—like alcohol is not for everybody—but this is a plant that has been used for 10,000 years and no-one has ever died. There has not been one recorded death. So why is it that we are treating it like this terrifying plant and it has to go through so many tests, like pharmaceutical drugs? For me, it is just crazy. I feel like we are being held to ransom by the TGA and these tests. I think it is about vested interests. The TGA board have representatives of the pharmaceutical industry. It is in their interests and in the interests of their profits to keep cannabis out of the market. I think that is a big thing.

A big issue for doctors is that not many doctors have experience with cannabis or much knowledge. The underground cannabis culture industry in Australia is massive. It is very hidden and very underground and, obviously, people don't want to expose it or talk about it. Use is really widespread. A lot of people have been using it for a long time. Like me, that is the medicine they have got used to—and we are still totally criminal. That is a real pity.

Education is a huge issue. In Australian culture, most young people smoke it with tobacco—which is a real issue. If you start smoking bong, you soon wake up in the morning saying, 'I want a cone.' It is the tobacco which is really addictive; cannabis is not physically addictive. I know myself that you can stop smoking cannabis and you might not sleep as well, but it is no big deal. I'd love education to happen properly for young people.

Organised crime, and unorganised crime, loves this. All the publicity about cannabis in the last 10 years has made the market boom. Most people aren't getting it legally. It has just helped the illegal market happen. Doctors and clinics are starting to happen a bit, but they tell me that 50 per cent of their work is giving advice on people getting illegal cannabis, how they should dose and what they should use. That is really interesting for me. You've all heard how much more expensive it is legally. They are the main points I wanted to make.

CHAIR: Thank you. We will now go to questions.

Senator URQUHART: I might go to Ms Cleaver first. Can you just talk us through the process of Jeremy's application for cannabinoid medicine and why that was rejected, as you outlined in your submission?

Ms Cleaver: Jeremy's neurologist had his application even before the scheme rolled out. So we were ready to roll in July 2017 and the controlled access scheme opened in September 2017. There was a lot of toing and froing in those first few months. The neurologist was telling us that the panel that makes these decisions here in Tasmania was advising him, firstly, what to prescribe, so he changed the initial prescription that he made for Jeremy to a cheaper product. His words were 'because it was cheaper'. There was a lot of confusion, because we couldn't speak to the panel and the neurologist was really busy, so it ended up blowing out to over 12 months before we had an answer on Jeremy's application. It came back that, in order for Jeremy to be eligible for the state's controlled access scheme, he must try and fail all conventional anticonvulsant drugs. At the time we started cannabis we were already being told that the neurologist had nothing to prescribe, that he'd emptied his toolbox. So, that the panel should determine that Jeremy should try these other drugs didn't seem acceptable and didn't seem right.

We did try to apply again and got the same answer, so basically at the moment we're being forced to choose between doing what we're doing illegally or torturing him further with medicines that are not going to be effective and, most likely, will be very detrimental to his health.

Senator URQUHART: With regard to the access to pathways not working for you: is that because of the difficulty with Tasmania not signing up to the streamlining process, or are there other barriers?

Ms Cleaver: Obviously, we hadn't signed up to the streamlined process, but it's because of how we access it through the specialists in the Tasmanian hospitals. We waited 12 months just for a neurologist at Launceston General Hospital. Access to the specialist is extremely difficult. If the system were to stay the same, definitely GPs would need to be able to prescribe.

Senator URQUHART: Okay. I was going to ask you how we could improve that system. Obviously, it's a process of signing up to the streamlining, but is it also a process of allowing GPs to prescribe the medicinal cannabis?

Ms Cleaver: That's right. But for us and for many like us you could improve the system by registering us to cultivate our own medicine, like we're doing now, and by giving us access to lab testing.

Senator URQUHART: Can you talk a little bit about what you're actually doing and how that works for Jeremy.

Ms Cleaver: Our hand was forced. We were buying it illegally and the supply ceased, so we started cultivating Jeremy's medicines ourselves. That was a process of learning about the different cultivars of cannabis. The benefits for Jeremy were almost immediate. His sleep patterns improved, his behaviour improved, and his seizures were less intense and less frequent. But also, because we were cultivating ourselves, we were able to start juicing the raw plants for him, and I cannot even begin to describe to you the health benefits from that. Of course, we do make tinctures and oils, but over the growing season he has access to fresh, organic cannabis straight from our garden, which benefits him daily.

Senator URQUHART: How have you worked out the best prescribed dosage? Has that been just trial and error? Have you been guided by doctors and treating specialists? How have you worked that process through?

Ms Cleaver: Unfortunately, because of the way we're doing this, our doctors can't advise. Yes, it has been trial and error. We've looked to other jurisdictions where cannabis is far more accessible than it is here in Australia, and we've gone the way of using cultivars that are good for Jeremy symptoms. So, yes, it's a bit of a process. I don't think Jeremy will ever be seizure free, but his quality of life has improved no end. So it's worth it even with the risk.

Senator URQUHART: And your quality of life along with that, I guess.

Ms Cleaver: Yes. There are pros and cons, of course. We still fear that we can't call the police if we need to. If somebody breaks into our house, the police will come to our back door and they can see our medicine garden. Everybody can see our medicine garden. The fear of his medicine being confiscated rules our lives pretty much daily. It would be nice to have protections around that.

Senator URQUHART: We know there are some difficulties in Tasmania. You've said you had to wait almost 12 months to get in to see a specialist. You obviously move around the community quite a bit. What numbers of people facing difficulty are we looking at, that you're aware of?

Ms Cleaver: I think the last report was that 11 patients were legally accessing, through the controlled access scheme. Hundreds, thousands, of Tasmanians are doing exactly what we're doing or buying cannabis down a dark alley or online, or importing it. With just under 12 patients having the benefit of doing this legally, you'd have to expect that there'd be many more thousands who are facing barriers.

Senator URQUHART: Okay.

Senator BILYK: Ms Cleaver, what role does the Tasmanian Medicines Access Advisory Committee play in Jeremy being able or not being able to get a prescription? Have they got the ability to override?

Ms Cleaver: They have overridden. We've had two neurologists want to prescribe for Jeremy, and TMAAC, the panel, have overridden the decision. It's a little bit secretive; I'm not really sure what they do. From my limited understanding, they approve all S8 medicines in Tasmania that are run through the Tasmanian health system and dispensed from Tasmanian pharmacies in the hospitals.

Senator BILYK: Thanks for that.

Senator ASKEW: In your submission, Ms Cleaver, I noticed that you talked about the fact that there is room for a tiered model. I was wondering how you would see that working with regard to pharmaceutical grade cannabis and cannabis products, herbalist/dispensary and self-supply. Are you talking about just medicinal cannabis in that case?

Ms Cleaver: Any cannabis product. If you look at other jurisdictions—in the States, a doctor gives a patient an authority to use a cannabis product. The patient goes into a dispensary and then the dispensary can decide what sort of cannabis product they want to try. Not everybody is like us; they don't want to home-grow or they can't home-grow. I appreciate that a lot of people want a nice shiny bottle of cannabis medicine that they're going to have to sell a kidney to afford. There's no reason at all why it can't be tiered. It has to move forward; otherwise people like us are going to remain outside of the law.

Senator ASKEW: Thank you. Mr Balderstone, you mentioned earlier that, at a personal level, you were using cannabis on a daily basis. Out of interest more than anything, over the last 30 years, is that something that you need to adjust the amount for or do you still use the same amount as when you first started to manage your symptoms? How does that work?

Mr Balderstone: I use the same amount. People smoke because it's like a self-titration; you can feel the effects straight away, so you know how much to use. It's one of the weaknesses with using cannabis orally; it

takes an hour to kick in, so you can have too much or too little. Once you've got a consistent form of medicine, then you can work out your dose.

Can I back what Lyn said on a couple of things: if we could test medical cannabis in Australia, it would be fantastic. The Southern Cross uni up north has got all the equipment, but no-one can test it. It would be wonderful if we could test it.

Senator ASKEW: Do you have a medical provider overseeing your use of cannabis?

Mr Balderstone: A medical provider? No.

Senator ASKEW: So no GPs or anyone to consult with?

Mr Balderstone: No. But we obviously talk to GPs. We have lots of GPs who are friends and who come and talk. We have Mardi Gras every year and different events that doctors come and talk to.

Senator DI NATALE: You mentioned testing. Obviously there's a huge profile of different drugs and different ratios of the various compounds within medicinal cannabis, and one of the challenges is that people who are being supplied a drug illicitly don't know what they're getting. The argument therefore is to regulate so that people can get a very clear idea of what they're getting and when a recommendation for a particular product is made we're sure that that's what's being dispensed. Where, for example, you've got illicit suppliers providing the drug, how does that deal with that problem of making sure we've got quality controlled product?

Mr Balderstone: A lot of people send stuff to America to get tested. Generally it's not tested. People who are supplying medical cannabis try to keep it consistent. But testing also for contaminants would be fantastic, to be able to know what you're getting—what it is. It would be perhaps easier, I think, for people who are using to be allowed to test their product. That would be a great way in. Obviously, suppliers and growers are pretty scared to come out themselves.

Senator DI NATALE: How big do you think the market is?

Mr Balderstone: Much more than 100,000 people. It's huge. In the 30 years I've been in the hemp embassy, I've talked to not hundreds but thousands of people who've got amazing results from using cannabis. Often people get really angry. They've spent 30 or 40 or 50 years suffering from something, and trying every pharmaceutical or whatever. Suddenly they try cannabis—and it can be like magic—and they get furious: 'I've spent my life suffering! I could've done this.' It's not for everyone, but, for some things, it's quite amazing.

Senator DI NATALE: What would be the most common health reason for someone wanting to access an illicit supplier?

Mr Balderstone: Nowadays, it's anxiety and stress, and the word's out there that CBD may help. It doesn't help everyone. Anxiety, stress and depression have become a big thing in our society now, and a lot of people are wanting to try it for those—and cancer treatments also.

Senator DI NATALE: Ms Cleaver, you said you were prescribed or recommended a couple of formulations from your neurologist. How much would they have cost you?

Ms Cleaver: The neurologist that did the first prescription told us that for Jeremy an annual cost would be between \$60,000 and \$100,000.

Senator DI NATALE: An annual cost?

Ms Cleaver: It costs us \$20 a week.

CHAIR: Thank you very much, both of you, for your evidence today. It's very much appreciated.

Proceedings suspended from 11:58 to 13:03

ARNOLD, Associate Professor Jonathon, Deputy Academic Director, Lambert Initiative for Cannabinoid Therapeutics, University of Sydney

McGREGOR, Professor Iain, Academic Director, Lambert Initiative for Cannabinoid Therapeutics, University of Sydney

CHAIR: I welcome representatives from the Lambert Initiative for Cannabinoid Therapeutics at the University of Sydney. Thank you very much for coming. I know you've been here listening and know that we've got a lot of senators who are very interested in the issue. And we do have your submission, thank you very much. I invite one or both of you to make a brief opening statement, and then we'll ask you lots of questions.

Prof. McGregor: We're a research centre looking at the cannabinoids. We were set up with an unprecedented donation from the Lambert family, who have a lived experience of medicinal cannabis that is very much like other stories you've already heard today. The granddaughter of Barry and Joy has a severe form of epilepsy, but they found great success using an illicit cannabis based preparation. It transformed Katelyn's wellbeing and engendered a very strong motivation amongst Katelyn's grandparents, Barry and Joy, to alleviate suffering in the community more generally with cannabis based medicines. That gave rise to this very large donation. To the credit of the Lamberts, they basically didn't put any ties on that donation; they basically said, 'Just do really good science to alleviate human suffering.'

A large part of what we do is what you might call cannabinoids of the future. When you deconvolute the plant there are more than 140 different cannabinoids. We really only know a lot about THC and CBD, but we do systematic interrogation of at least another 20 of the cannabinoids. We look into animal models and cellular models of cancer, pain, mental health conditions, addiction, and so on and so forth. We've made some remarkable discoveries. In a way, we think of ourselves as cannabis 3.0. There's traditional cannabis, and there's cannabis 2.0, which is THC and CBD in our experience now. We're sort of the cannabinoids of the future. It's a very, very exciting frontier in science. This is perhaps the most exciting frontier in pharmacology and medicine at this moment in time.

It's not just the cannabis plant itself; it's also our knowledge of the endocannabinoid system, which you've also heard about today. We're doing all this preclinical research, and at the same time we're running a fair number of clinical trials with existing cannabis based medicines to try and build the evidence base. We pick areas where that evidence base is particularly scant. We're doing clinical trials, for example, in youth anxiety. We have quite remarkable effects with youth mental health in a trial we recently concluded with CBD. We're also working on alcohol withdrawal. We have plans for work on ice addiction in 2020 using CBD, coming from our preclinical research showing a strong sign there. Also neurodegenerative conditions, particularly agitation and dementia. We see this vast, untapped potential with cannabinoid based medicines, and we're keen to build that evidence base.

The third part of what we do, and what will probably interest you the most, is a lot of community based work. You heard a little bit from Carol Ireland about our PELICAN survey, where we worked with families in the community who have children suffering from epilepsy who were using illicit artisanal products. We work closely with these families to look at the perceived efficacy of the oils they were using, and we also did chemical analysis of the oils and showed a major disconnection between what parents thought were in the oils and what actually was in them. This is the jeopardy, if you like, of parents treating their children: they don't really have any control over cannabinoid content or quality.

We've also done a number of surveys that were mentioned in the submission, highlighting that, if you take a thousand people that are self-medicating with cannabis in Australia, for example, our estimate is that maybe only three per cent of them are going through TGA schemes at the moment. We've just completed a major survey of that. We've also done a survey on inflammatory bowel disease, where only three out of 212 cannabis users were actually getting TGA approved medication. Our evidence is very much that there is vast use of illicit artisanal products, despite the best efforts of the official schemes that are underway.

There are two other things I will mention that are particularly interesting. One is our work on driving. We've done a lot of studies on driving, and several are ongoing. We're currently working with the Netherlands on an on-road driving study, where people are vaporising cannabis with different formulations, and we have a driving instructor next to them with dual controls. We're getting a very fine-grained analysis of what different types of cannabis are doing to driving. We've also looked at roadside drug-testing technologies and have shown them to be pretty much insensitive and inaccurate, which is a major issue in the community.

The final thing that interests us is alternative models, and particularly the idea that low to medium doses of CBD could become over-the-counter products. My colleague Jonathon has worked on the expert committee of the

World Health Organization looking at CBD and possibly moving CBD out of existing schedules to become—what's the right word, Jonathon?

Prof. Arnold: Descheduled.

Prof. McGregor: Descheduled, yes. If you go to the UK, if you go to Germany, if you go to Switzerland, Canada or the USA, you can walk into any pharmacy and get low-dose CBD products. We think that could be a game changer for Australia if we can get it descheduled. That will at least allow patients to have easy access to CBD products that are relatively cheap, and they can trial them on their condition without risk of criminal sanctions. If they work, very good, and if they don't then we can move on to some alternatives. We see that as maybe a relatively easy route to greatly improve patient access and one that could be quite easily implemented.

CHAIR: Thank you. Professor Arnold, do you want to add anything?

Prof. Arnold: I would just like to expand a little bit further on what Iain was saying about the World Health Organization recommendations. In 2018, I was a temporary adviser to the WHO on their first-ever review of cannabis and cannabinoids. They did this as part of the work of the Expert Committee on Drug Dependence. They reviewed the evidence of the therapeutic, toxicological and epidemiological effects of cannabis and cannabinoids in building the recommendations they've since made to the United Nations.

I'd like to draw your attention to those WHO recommendations, one of which is that cannabis should be deleted from schedule IV of the Single Convention on Narcotic Drugs. That's the prohibition schedule. It exerts the tightest control, according to those conventions. That was one of their recommendations. The knock-on effect of the United Nations voting in favour of the recommendations would be that it would to an extent free up not only patient access but also our ability to do scientific research on cannabis and cannabinoids.

The other major recommendation was that cannabidiol not be scheduled at all. Cannabidiol is the non-psychoactive constituent of cannabis that appears to be really effective, based on some trials that have been conducted, in reducing seizures in childhood epilepsy. Based on the review of the evidence, they concluded that cannabidiol is a relatively safe compound.

Senator DI NATALE: Is CBD a shorthand way of describing—

Prof. Arnold: CBD is the shorthand way, yes. I'll use the shorthand version of cannabidiol from now on. Like I said, CBD isn't psychoactive, but it's also not prone to drug dependence. They didn't see it having a place in those conventions, and they recommended that cannabidiol preparations containing no more than 0.2 percent THC not be subject to international drug control.

I think Australia has an opportunity to vote in favour of these recommendations. Australia will be represented at an upcoming meeting of the UN Commission on Narcotic Drugs, which might vote on this as early as March. The vote has been postponed, but it might come up in March. I would plead with you to see what can be done about Australia voting in favour of those recommendations. They're all scientifically based recommendations. World-leading scientists and clinicians came together to formulate the evidence base from which the WHO drew their conclusions and recommendations.

CHAIR: Thank you. Senator Di Natale, do you want to kick off this time?

Senator DI NATALE: Thank you. Your Cannabis as Medicine Survey outlines that only about three percent of the community are accessing cannabis through legal pathways. Tell us a bit more about that.

Prof. McGregor: This survey was done between September 2018 and March 2019. We do accept that the number of approvals has increased a lot since then. At that particular time, most of the participants in the survey had been recruited in 2019, between January and March. Our submission outlines some of the key results. Twenty-five out of 931 respondents were getting TGA-approved medicinal cannabis. More than 90 percent thought that the current regulatory framework did not work well, more than 60 per cent said that the cost was prohibitively expensive and almost 90 per cent said that the current access model was extremely difficult for patients to negotiate. We were actually quite surprised. At that moment in time we thought that we would perhaps have a more sizeable percentage for TGA products. We did a more recent survey of just inflammatory bowel disease patients, and they recapitulated these results. Only about 1.5 per cent were getting TGA products at that moment in time. That's what these surveys are telling us, that there's still a major disconnect between the official scheme and what's happening in the community. You can criticise it for being a self-selected sample, but, at least in our IBD survey, 75 per cent of the people we recruited were not cannabis users, so it was a very representative sample.

Senator DI NATALE: In terms of the survey of medical professionals, we've had a lot of discussion about why GPs aren't prescribing more of it. You seem to indicate that GPs have actually got a fairly good appetite for wanting to learn a bit more about it and prescribing it. Can you explain that?

Prof. McGregor: We conducted what I think is the only survey of Australian GPs in 2018, and there were 640 GPs who responded. A clear majority were in favour of having medicinal cannabis as an option that they could prescribe, but they did not feel comfortable talking to their patients about it, because they didn't feel well educated; they didn't feel that they had adequate knowledge of access pathways. When we asked them how harmful they rated medicinal cannabis relative to existing prescription medications that they very commonly prescribe, they said that they felt medicinal cannabis was safer than opioids, benzodiazepines, antidepressants, antipsychotics and even statins—of the ones who expressed a preference. So they perceive it as being safe and they want to have it in their doctor's bag, if you will, but they feel uneducated. We obviously have to put our thinking caps on around how to systematically educate this body of doctors. We do our bit—I do a lot of educational events with medical practitioners. But I noticed that the New Zealand government has actually called for a tender for an educational program for GPs in that country, and I think that would be a very welcome addition in Australia.

Senator DI NATALE: You mentioned that one of the areas you're looking at is youth mental health and the use of some additional cannabis products. People would be surprised to hear that, because people often cite the impact on mental health and psychosis and so on as a result of the use of cannabis type products. Could you perhaps explain why you're looking at the use of medicinal cannabis products as a treatment for some mental health conditions?

Prof. McGregor: This goes back to the difference between THC and CBD. The product that we've been working with is CBD only—cannabidiol. We've just finished a trial here in Melbourne with former Australian of the Year Pat McGorry and his colleague Paul Amminger. These were severely anxious young people aged between 12 and 25—kids who couldn't get out of the house because they were so anxious. They couldn't go to university or school and they couldn't hold down part-time jobs. We gave them 12 weeks of CBD, titrating up to 800 milligrams, and we got highly significant results in terms of reduction of anxiety at that 12-week time point. This is a bit of a game changer. I'll acknowledge that this wasn't a placebo-controlled trial—that's our next plan. It was basically what we call an 'open-label trial' to have an initial look. But there is also another very interesting trial that we'll launch this year with the same group, which is looking at early psychosis. These are kids who are starting to show signs of becoming schizophrenic, and there's already a bit of literature suggesting that CBD can have quite strong antipsychotic effects. This is a program that's being funded by the Wellcome Trust in the UK—a large placebo-controlled trial where we'll give CBD to these kids who are at high risk of psychosis and see if it prevents them from transitioning into schizophrenia.

Senator DI NATALE: That's obviously very interesting given that it's being used as a treatment, as opposed to much of the public conversation where people are worried about it being a cause of psychosis. I think it's very important to raise that. You mentioned the vote around whether CBD—I think it's the UN—

Prof. Arnold: Convention on narcotics?

Senator DI NATALE: Yes, the Single Convention on Narcotic Drugs. Has the Australian government, as far as you're aware, indicated a position on that—whether they're prepared to deschedule or not?

Prof. Arnold: Not to my knowledge, and the reason I have sought to emphasise that is that I think it is something that needs to be discussed and, ideally, have a position made on it.

Senator DI NATALE: And you think that the effect of this would be that there would be no need to go through this convoluted process of applying to get a prescription for it and that, if it is descheduled, obviously availability changes? Dr Skerritt, I see you in the audience. You have shaken your head a lot today. I think it is being very disrespectful to many of the witnesses, actually—because I see you shaking your head furiously. You will have your opportunity to put your contribution on the table when we hear from you, but I think the witnesses would appreciate you perhaps not engaging in that show of disagreement publicly. Professor McGregor and Professor Arnold, would you like to perhaps speak to that—not that specifically, but the issue of CBD being descheduled.

Prof. Arnold: What happens in Australia is really up to Australia and how it goes with it. But, in terms of the convention that Australia is a signatory to, it could change and loosen up the current restrictions on cannabis. Of course, CBD would not be scheduled under drug control, but, with the local regulations, there would be a need to look at what would happen there.

Senator DI NATALE: Thank you.

Senator ASKEW: I have a couple of questions regarding your submission. You were talking about the Office of Drug Control and said that your mission has been to 'source locally produced cannabinoid products and related molecules', and you then go on to explain the difficulty of accessing them from international sources. Could you elaborate a little bit on that for me? It is on page 8 of your submission.

Prof. McGregor: A recurrent issue that we have is to source products for our clinical trials. We have a portfolio of clinical trials underway. We prefer to partner with Australian companies, but often they don't have the product; so we also work with Canadian companies and Dutch companies. An issue has been the length of time that it takes to organise importation from the ODC level. It is nothing compared to the delays for cultivation and research licences, which can extend to two years in some places, I've heard. But four to eight weeks can be very inconvenient. The CBD being removed from international treaties and there being no import or export requirements might facilitate our trials. The ideal solution, of course, would be to be able to source all our products within Australia. In fact, in our deed of gift at the Lambert Initiative from our philanthropists, they express a very strong preference that we always use Australian sourced products where feasible.

I think this points to some of the problems that the local industry has that have been alluded to in the inquiry already this morning in terms of the costs of getting set up and the barriers. Certainly, when it comes to industrial hemp, there is no real argument whatsoever for industrial hemp for medicinal purposes being in a highly secure unit that takes \$20 million to build. I cannot see any sense with that approach. Hemp could be a great earner for Australia. It's a great crop. It is relatively drought resistant. With cotton struggling, you wonder whether hemp could be doing a lot better.

Senator ASKEW: An issue you touched on earlier was the legalisation of the illegal activity of driving with CBD in your system. In your submission you say: 'Our recent research in this area shows that cannabis can impair driving under demanding conditions,' and then go on to say that it's not as bad as being over 0.5. What sorts of demanding conditions are you talking about in that sense?

Prof. McGregor: Cannabis and driving is actually a very complicated area. The tendency is to look at it through the prism of alcohol, but there are actually almost diametrically opposite effects for cannabis relative to alcohol. With alcohol, people overestimate their ability and tend to take risks as a result. With cannabis, people actually feel impaired. Often they don't want to drive in our road trials, and we don't compel them to drive if they don't want to. When they do drive, there are quite reliable effects like a lower speed and a bigger distance between them and the car in front. Then, when you look at the crash risk associated with cannabis, it's moderately increased but it's a very, very small statistical effect compared to alcohol and even compared to some prescription medications that are commonly prescribed like benzodiazepines and sedating antidepressants like mirtazapine. We have problems recruiting patients to our clinical trials involving THC when they hear that they can't drive for 12 weeks. This is a major issue. I think that what patients want is clarity around when it's safe to drive. Other jurisdictions will say you have to leave it for four hours or you have to leave it for six hours. Our best guess at the moment is that probably six hours is safe. So we need to be much more enlightened on the information that we present to patients around driving.

We also have to be really careful about oral fluid testing, or saliva testing, because the relationship between oral THC and driving impairment is very, very remote. You can have THC in your saliva and drive absolutely perfectly. Again, patients need to be given an informed position. They may have THC in their saliva because they have been using a medicinal cannabis product for the last two years. Fair enough. Are they safe to drive? They probably are. Another really important thing about cannabis and driving is that you get tolerance of the impairing effects on driving. If you give someone cannabis for the first time, they'll be very impaired for a couple of hours after consumption, but, if someone is a patient and they have used cannabis for two years, chronically every day, you will really struggle to find any sort of impairment whatsoever. So we need more research and we need more enlightened information for patients rather than just saying: 'Don't drive.'

Senator ASKEW: Thank you.

Senator BILYK: There was the survey that you conducted in 2018. You've already talked a little bit about this. It showed that the majority of GPs support medicinal cannabis. It also found that specialists are more conservative. Could you expand on that for us and why you think that is?

Prof. McGregor: Yes. It's interesting. We have a very recent survey from gastroenterologists. It hasn't even been published yet. Only seven per cent of them thought that IBD patients should be using medicinal cannabis and only five per cent wanted to prescribe. So they're very conservative compared to the GPs. When you get into specialities, you can do a deep dive into the evidence base. On IBD, there have been maybe four or five clinical trials involving a very small number of patients, and there are relatively inconclusive results. It could be that they're aware of the minimal evidence base. What's more likely, however, to come out of our surveys is that they

have no knowledge of products, they have no knowledge of dose titration, they have no knowledge of what to do with their—

Senator BILYK: The specialists or the patients?

Prof. McGregor: The specialists. Even though their patients are often asking them about it, they're not in a position where they're educated. It's a very odd disconnect. The gastroenterologist rated medicinal cannabis as less harmful than a lot of the drugs that are commonly prescribed—biological agents, opioids and so on—yet they still didn't want to prescribe it. It's probably a lack of confidence coupled with a lack of available evidence and coupled with, maybe, conservatism within the colleges as well.

Senator BILYK: Regarding the four or five clinical trials you just mentioned, do you know where they were undertaken? Were they in Australia or overseas?

Prof. McGregor: The IBD clinical trials?

Senator BILYK: Yes.

Prof. McGregor: They were done mostly in North America.

Senator BILYK: Are there any clinical trials being undertaken in Australia with regard to medicinal cannabis?

Prof. McGregor: Yes. We run four ourselves, with another three. I think the TGA submission mentions maybe 80 or 90.

Senator BILYK: Are there any barriers in relation to those?

Prof. McGregor: It's probably easier to put a dog on the moon than it is to get a cannabis clinical trial up and running. Sorry—that's a bit facetious!

Senator BILYK: I had my own bit of sarcasm earlier!

Prof. McGregor: Certainly in the early days we really struggled with ethics committees, for example. Sourcing product has always been a challenge, as I've already mentioned.

Senator BILYK: Do you import?

Prof. McGregor: Yes, that's right. Importation can be—

Senator BILYK: And why do you import rather than use Australian—

Prof. McGregor: Because the local industry isn't mature enough to provide the quality assured products. It's the same with patient access under SAS B.

Senator BILYK: Just to go back to my last question, what do you think we need to do to be able to make it easier for the Australian market, for lack of a better word, to be able to mature?

Prof. McGregor: Well, in a way that's a question for industry. We're scientists, but we'd certainly like to see a much more vibrant industrial hemp industry that's actually devoted more to CBD production. This is what you see in the US. If we can partner that with nutraceutical CBD markets—so if we take CBD out of schedule 4, put it in schedule 2 or schedule 3, or even treat it as a complementary medicine—then that would allow a local industry to really thrive in terms of supplying that much broader, much more open market which, let's face it, is completely compliant with where the WHO is heading at the moment—that is, to remove CBD from international treaties and drug control.

Senator BILYK: Some of our submissions mention concerns with regard to resourcing for the Office of Drug Control. Have you had any feedback or information with regard to that?

Prof. McGregor: This is an industrywide problem, and we also have our own issues whenever we want to bring in drugs for clinical trials. Sometimes we bring in milligram amounts of a particular cannabinoid to test on cancer cells or whatever, and the amount of time it takes to get import and export organised is much longer than it should be, particularly for milligram amounts where there is no risk of diversion or intoxication. This is just a tester for cells or to use the standards in our analytical chemistry. So there is a range of issues there.

Senator BILYK: You mentioned delays, so how long might it take to import a couple of milligrams?

Prof. McGregor: We had a recent case where we were just trying to bring over five milligrams, I think, of a particular standard from New Zealand. This was a non-intoxicant; it was one of the CBD metabolites. There is no risk of diversion or intoxication, but it's taken us two months to organise that. It's for the trial on youth anxiety that I mentioned earlier, and it's quite an important thing for us to be able to analyse CBD metabolites in the bloods of these young people who are also on other medications, including antidepressants. So that really held up

our ability to publish that study and to disseminate information about our study while we waited two months to get that importation permit.

Senator BILYK: Has that study been published now?

Prof. McGregor: No, it will be another couple of months, but we're happy to supply the committee members with further information as soon as it comes to hand.

Senator BILYK: Thanks.

Senator URQUHART: Professor Arnold, you earlier talked about the WHO recommendations, and you urged Australia to vote in favour of removing—that it be deleted from schedule 4. What would be the justification for Australia to vote against that?

Prof. Arnold: I'm not saying vote against it; I'd vote for it.

Senator URQUHART: I get that, yes, but, if Australia were to say no, what would be the justification? What would they use as the rationale for that?

Prof. Arnold: I guess the rationale would be that cannabis is as harmful and without any therapeutic merit, and it would be a similar categorisation to heroin.

Senator URQUHART: But your trials have shown something different—is that the case?

Prof. Arnold: Yes. I guess a counterargument from potential parties would be that cannabis doesn't have any therapeutic effects, and it's really, really dangerous.

Senator URQUHART: But yet we're seeing lots of therapeutic effects.

Prof. Arnold: Yes, and I obviously don't hold that viewpoint.

Senator URQUHART: Yes, of course.

Prof. McGregor: If I can interject there—

Senator URQUHART: Yes, absolutely!

Prof. McGregor: one other argument that we hear about CBD is that it may have adverse interactions with other prescription medications, and that's certainly something that the TGA has espoused. In response to that, I would say that there are numerous prescription drugs and complementary medicines that interact with other drugs. It's a risk that can easily be managed and shouldn't necessarily be a red flag. We know of no fatalities relating to CBD's adverse interactions with other drugs. We have an adverse drugs reactions database that TGA runs. Perhaps you can ask Professor Skerritt whether there are any instances in that database where CBD has been responsible for adverse drug reactions.

Senator DI NATALE: I have a very quick question in relation to the TGA, from your submission. I meant to ask this earlier. As to the issues around getting information—data—from the TGA in terms of your research, can you just speak to those quickly?

Prof. McGregor: Yes. We're fascinated, because we see the green market a lot in the surveys we do and we also see the official market, so we're always very keen to get the latest data from the TGA around approvals, and it's quite a rich dataset that they hold. We're compelled to use freedom of information legislation to access these data. It can take eight weeks to get the data. It costs several hundred dollars, which is not a major issue for us but could be an issue for other parties. We also regularly find inaccuracies in the data that are presented. Now, I realise that they have a tough job to do and they're probably not optimally staffed, but we would like to see them have an open and transparent database of all the information that they collect. Obviously, patient confidentiality has to be honoured as well. But there is very rich data that could be made available to researchers and to the community more generally very easily. They already give us monthly approvals on their website. I think a much richer dataset could be provided, and we shouldn't have to struggle and pay to get these data as we do at the moment. And it's a very fast-moving field. Every month maybe 3,000 more patients are added. So we don't want to wait two months to get the latest data.

Prof. Arnold: I would just add to that that the submission by the TGA did have a lot of detailed information in it, and I thought it was fantastic—all that information being provided—but if that could be provided on an ongoing basis that would be very helpful.

Senator DI NATALE: In real time?

Prof. Arnold: Yes.

CHAIR: I'm going to have to wind us up. I'm sure you'll follow that up later on this afternoon. Thank you very much for your evidence today. It's very much appreciated.

BARTONE, Dr Tony, President, Australian Medical Association

NESPOLON, Dr Harry, President, Royal Australian College of General Practitioners

SPEAKMAN, Dr David, Expert Adviser, Clinical Oncology Society of Australia Ltd

Evidence from Dr Nespolon was taken via teleconference—

[13:37]

CHAIR: Welcome. Thank you for coming. For those of you who haven't been here earlier, you've probably seen from the hearing schedule that we have a very heavy schedule, so I'm trying to keep us as much as possible to time. That relates to the fact that I'm inviting people to make an opening statement but asking them to keep it fairly short, please. First, is there anything you would like to add about the capacity in which you appear today?

Dr Speakman: I'm a member of the council of the Clinical Oncology Society of Australia and that's why I'm here. I should probably declare that I was also on the Victorian ministerial advisory committee on medicinal cannabis.

CHAIR: Dr Speakman, I'll invite you to make a short opening statement and then I'll invite the others to do so, and then we'll get started on some questions.

Dr Speakman: Thanks for the opportunity for COSA to be here. We fully support the work of your committee. COSA will put in a written submission. We have not done that yet. I think the closing date is yet to come. Essentially, we've had a position statement around the use of medicinal cannabis in cancer for quite some time. As an opening statement, it would be fair to say: COSA would suggest that there's no published evidence supporting the use of medicinal cannabis as a cure or treatment for cancer. However, it fully acknowledges that there is a role for medicinal cannabis in relation to the side effects and results of both cancer itself and the treatments of cancer. We'd fully support ongoing investigation into exactly where medicinal cannabis fits in that arena.

CHAIR: Thank you. Dr Bartone?

Dr Bartone: I'll try to keep it very brief, because of your request. The AMA certainly recognises that cannabis has potential therapeutic uses. We support the appropriate clinical trials of therapeutic cannabinoids to determine their safety and efficacy compared to existing medicines. However, when the legislation on medicinal cannabis was first mooted, we cautioned that it was still not clear how the medicinal cannabis system would operate. We cautioned that there was a paucity of information from government which added to the confusion. That was nearly two years ago. Today, it's still mystifying as to how many medicinal cannabis products will be dispensed, what products are available and how effective some of the products are for treating and managing the specified medical conditions.

While there's widespread interest in medicinal cannabis, there's still insufficient information on its efficacy, product availability and education regarding its use. In particular, we are of the view that medicinal cannabis should only be prescribed as a last resort or strictly in regulated circumstances. It's appropriate to say that what we're being told is that patients might be using the option of a black market, and that is also of concern to us. The concern is that the system is so convoluted and complicated for patients and prescribers that it isn't fulfilling the reason for which it was established in the first place.

It seems to us that what has happened here is that the government has jumped the gun with medicinal cannabis. The public have an expectation, or have been led to believe, that medicinal cannabis is now available and patients can go to any clinic or any doctor and it will be prescribed. This creates many problems for both GPs and patients, and AMA members have told me that they're hearing conflicting information about the use of medicinal cannabis as a pain relief medication, for example. Anecdotally, we have frustrations amongst GPs that they're not being sufficiently informed about what cannabis products are available and for what conditions. Every day, it seems, there are new reports and findings relating to medicinal cannabis, and therefore the need for up-to-date information and education is paramount.

When we asked our members about barriers, they agreed with the proposition that one of the biggest barriers to accessing medicinal cannabis treatment options for patients is the current regulatory barriers, which included the complexity, time and paperwork involved in prescribing, the cost of medicinal cannabis, and doctors not being informed to the point of being confident enough to prescribe. Concerns were also raised by some AMA members regarding the evidence from the clinical trials and how this evidence has been used to inform the scheduling of cannabis as a medication. The cost of medicinal cannabis products is also a barrier to their use, as is the lengthy time for filling in the complicated forms.

Doctors are also having issues finding the time to undergo the training and accreditation, and it's one of the other reasons why medical practitioners might be reluctant to prescribe medicinal cannabis to patients. We know—anecdotally again—that many GPs are interested in becoming accredited but, because of the way these sessions are set up and their accessibility in comparison to the GPs' time and availability, it becomes a really problematic exercise.

In the interests of time, I'll leave it there for any questions.

CHAIR: Thank you. Dr Nespolon, I invite you to make an opening statement.

Dr Nespolon: We'll be brief. From our perspective, one of the main issues associated with medicinal cannabis is the requirements for practitioners when they wish to prescribe it. The process is often quite complicated and can be quite daunting, especially when you're approaching it for the first time. The second issue is that medicinal cannabis requires further evaluation and investigation of whether or not it is a useful product for patients. But at the moment, under the current arrangement, it is being used as a treatment for patients, where all other treatments haven't worked. Finally, when it comes to accessibility there seem to be two groups of doctors at the moment. There are those who are keen to prescribe and are willing to try and get over the potential barriers when it comes to prescribing, and then there's probably a second group, who are a little bit sceptical about the potential benefits of medicinal cannabis. A lot of the things that Dr Bartone said are issues that our members are concerned about as well, so we support a lot of what Tony said.

CHAIR: Thank you very much.

Senator URQUHART: I will mainly ask the AMA and the royal college first. Are your members asking for training in relation to prescribing medicinal cannabis in terms of better understanding what their obligations are?

Dr Bartone: It's not so much what their obligations are. It's about understanding the actual product and the products available. Remember that there is still an emerging market, or a set of market options, in terms of medicinal cannabis. Let's just step back a bit. Normally when a product comes to market it's already gone through extensive multiphase clinical trials. It's had the benefit of some hospital based, or specialist based, experience. There's usually a program which delivers that product to market, and that includes the information distribution to ensure that everyone is comfortable when first prescribing it. This has absolutely not happened in this case. We've had the product being available to be prescribed—let alone the regulations around it—but without a lot of that having happened. So we're trying to backfill and bring up to speed in a very short space of time what normally would take a number of years, from go to whoa.

What GPs are asking for is an opportunity to be informed about exactly where the evidence is going. One of the reasons we're doing the clinical trials is to understand its efficacy and the actual formulations that are available and how they should be used. What are the dosage guidelines? You take X amount of this so many times in this way, and that's basically how you should be managing that condition. Even in the clinical trials prior to the current ones, we don't have the kind of robust data, and that's why we're having these clinical trials now—to give us that information. Essentially we're running at a parallel course at the same time. We're all trying to speed ourselves up to the information. That's part of the reason why there is (a) a certain reluctance but (b) a difficulty in accessing timely and reliable information, and that's the information that GPs want.

Senator BILYK: I will just clarify something. Not all GPs can prescribe though, can they? In Tasmania you have to be a specialist.

Dr Bartone: I wasn't aware of that, but clearly there are state guidelines. Clearly where there is the capacity for GPs to prescribe, which in the majority of states is through the special access schemes and the permits, that is an option. But, clearly, where state regulations do not allow it—of course not.

Dr Speakman: I just want to support what the AMA said about that. I think, even further, one of the things that's perhaps a bit invisible is the lack of clarity between what a standard dose is in one company's formulation against another company's and another company's. I've heard several anecdotes from prescribing doctors that, when one is not available through the TGA process, to go and find something you believe is equivalent is incredibly difficult. And what happens to the patient on the end of that? They may or may not be getting the same thing, or, indeed, they may wind up getting nothing even though we've tried to put a regulation in place already. I'm very supportive of the AMA's comments.

Senator URQUHART: Dr Nespolon?

Dr Nespolon: In relation to Tasmania, yes, we do find concerning that general practitioners are not able to prescribe medicinal cannabis in Tasmania. Part of the problem is that each of the states have different requirements for prescribing, although the mainland states seem to be becoming more uniform.

Following on from what Tony was saying: the problem is that there is a plethora of products in different forms and concentrations. I know that the New South Wales department of health has attempted to provide as much information as it can to improve the availability of medicinal cannabinoids. But there is still an issue for patients in the sense that they need to find a prescriber, because not all GPs are willing to prescribe at the moment. Part of that problem is the difficulty in the multitude of products. It's going to take time for GPs to become educated. The actual approval process can be quite daunting.

Senator URQUHART: How do GPs currently get information about products available on the Australian market?

Dr Nespolon: At the moment, a lot of that information does come from the producers of the products. You might argue that that's not that different from what happens with more mainstream pharmaceutical products, but trying to find independent information can be difficult.

Dr Bartone: To add further to that: we read journal articles and we're aware of what's coming through the pipeline. There is an anticipation that there is a new X, a new Y or a new Z coming through. We hear from our non-GP specialist colleagues in the hospital environment that they're having trials in their own hospitals of medications which are not yet used in private practice. Our non-GP specialist colleagues put patients on certain medications. That comes back to us and partially informs us about the rationale behind their use. There are ongoing education evenings and training run by universities and other companies, ensuring that we get some of that information as well. It's a plethora of sources. There is a machinery around those sources that does produce an end result of ensuring that, when a new medication does come to market, it has literature, information, training and opportunities for education around it available.

Senator URQUHART: Thank you.

Senator DI NATALE: Just on that specific thing: as a GP, you get your information from a variety of sources. You read journals. You have the evening meetings, most of them by drug companies who have got a big investment in a product that they've put through a regulatory process and big education budgets. We're not seeing that with medicinal cannabis. Is there anything structured at all? Is the College of General Practitioners, the AMA or anyone facilitating a structured program of education for GPs around medicinal cannabis?

Dr Bartone: The AMA has not got a specific structured program. We do have modules in that space available through our online learning portal, but there's no structured certification course that we run. I believe the College of GPs is running one; no doubt Harry will speak to that. There are many other opportunities through either research arms or other public institutions to allow that vetting process.

Senator DI NATALE: But aren't you saying that doctors are finding it harder to get appropriate education? I am trying to work out, if I'm a GP, where I go. As someone who became a methadone prescriber, I did a course and was approved to prescribe methadone. I don't want to compare methadone with medicinal cannabis, but it's an example. There were concerns, clearly, around opiates. What is there in general practice—

Dr Bartone: Sorry, I was answering on the existence of courses. The number and availability and the spread and the breadth of those courses nowhere near matches the broad popular demand. Then there's the time-poor nature of general practice, even though there is a demand for that information and that learning. Also, as we already alluded to, not every GP will be a prescriber because of their practice profile or their risk profile or because they will wait to see how the evidence evolves in the longer term.

Senator DI NATALE: Sure, but what if I'm a GP and I'm interested? I hear this as well from my colleagues, who are frustrated, and a lot of people who are interested in learning more about it. I suppose what I am asking is: given this is a new area and there is a big demand out there, what is out there that is structured in a way that allows a GP to become informed and educated around medicinal cannabis?

Dr Bartone: Apart from the areas I've highlighted, there is nothing else. This is particularly a role where the government could come in and facilitate—

Senator DI NATALE: You think there is a role there for government to fund some education?

Dr Bartone: I do believe there is a role to assist with funds or, with the partners that are available in the market, to ensure a wide dissemination of those education programs.

Senator DI NATALE: Dr Nespolon, you might want to also add to that.

Dr Nespolon: I can tell you what the college has been doing, particularly in New South Wales, as that's where I'm based. We have been running some webinars which have been attended by up to 300 GPs. So there is some real interest in being able to prescribe medicinal cannabis. I have also been to some of the company presentations

and also some relatively independent presentations by people who usually provide medical education. So there have been those three sources.

I'm not sure what the role of government would be in education, per se. At the end of the day, still at the moment it is relatively product-specific education, because the products aren't that substitutable. The other issue that you run into, I understand, is the availability of products. The products are not always available. That can be a problem for patients who are on a product for a particular period of time and then it becomes unavailable because they are not being able to get it into Australia. There are opportunities available to learn, but I guess they are not as broad as you would find with other groups of pharmaceutical products.

Senator HUGHES: Just quickly, we heard a bit earlier today about how we haven't seen the clinical trials and we don't have the data and background evidence. Other drugs are put through certain clinical trials, they are registered with the TGA and they are backed up by evidence, which makes it a simpler process for GPs and specialists to then prescribe them. I just wanted to get a bit of a sense of whether or not there is a benefit to that process continuing in that more clinical way versus how it has been coming out. I think I heard the mention of a parallel process at the moment with the clinical trial going on as products are launching and the lack of that information and the actual efficacy and data behind them. Taking a bit of a step back and going through that more official program and process might be more beneficial. Do you have any thoughts on that?

Dr Nespolon: I might just repeat what I said in my very brief opening comments. I think there are two groups of GPs out there. There are the ones who are willing to try medicinal cannabis with their, if I can call them this, very difficult patients, but there is also the other group, which is concerned about the lack of evidence for the use of medicinal cannabis in general but also its relative value in particular groups. There is better evidence in some clinical situations than others. But, if you're looking at the broadbrush approach, there are a lot of GPs who don't want to prescribe, because they don't believe that medicinal cannabis does have enough evidence behind it for them to be prescribing it for their patients.

Dr Bartone: I'll only add to that that basically the parallel processes are what's there at the moment. To change that at the moment would be to create even more confusion. We've got a situation that has already been in play for the best part of two years. We need to ensure that the clinical trials are robustly supported, resourced, informed and allowed to go to their natural conclusion. That will provide a significant amount of evidence one way or the other about the effectiveness of and the uses for medicinal cannabis and also the various formulations of medicinal cannabis and how they can be intersubstituted. That's part of the missing information that we desperately require for the local market, the local supplies which are also being provided. They need to be allowed to conclude. We've got the regulatory process in place. The TGA has served us well for many, many decades, if not longer. We've got one of the safest regulatory systems in the world. They should be allowed to do their job as well. They've tried to really backfill, as I can see it, the missing void to allow the confidence in the people prescribing medicinal cannabis and to the Australian community that are looking for that as an option for their care.

CHAIR: Dr Speakman, do you have anything to add?

Dr Speakman: No. I agree with everything that has been said.

Senator ASKEW: We're obviously hearing about all of the opposition and all the difficulties and things along the way to actually get to the prescription of medicinal cannabis, but in all three areas have you actually had success? Have you had feedback of any success and what the outcomes for the patients are? That's what it's all about in regard to the patients. Have there been problems along the way with the patients or has there been evidence that you're seeing on the ground or feedback through your organisations in regard to the prescription once they've actually been taken?

Dr Speakman: From an oncology point of view there's clearly the prime areas for us, which are around nausea and vomiting, appetite and pain as a result of your cancer or the treatment thereof—the current preparations we have available don't suit everybody and don't achieve resolution in everybody. Should we be investigating the role medicinal cannabis has to play? Absolutely. There's lots of anecdotal evidence about its benefits for some people in some situations. I think the thing for us, particularly in oncology, but, as you've heard, everywhere, is that usually we would have done trials and studies to see where it fit in, where the best place was and, indeed, in whom it's not safe to give. With that caveat it absolutely needs to continue to be explored. The anecdotes that are around indicate that we should continue to explore it.

Dr Bartone: I'd like to endorse everything Dr Speakman said. We know that there is evidence of varying degrees where those trials are in place. The anecdotal feedback—and it is only anecdotal—is that there have been some pluses and some minuses. Those trials need to be allowed to go to their conclusion, as normal trials should,

and should follow the ethic guidelines that have been put in place around those trials. At the same time, all the other steps of the process need to be looked at, including the production and commercialisation arms of the options available, and matching those two arms together in the therapeutic properties.

Dr Nespolon: If I have misunderstood the question, I apologise, but given the way that medicinal cannabis is being used at the moment outside the cancer groups—if I can focus on that—there is no doubt that there are patients who have really benefited from it. Anecdotally, patients who have been on long-term failed medication, especially in the area of pain, have benefited. But again this is anecdotal and, as it is, the patients who have come to the end of their traditional therapeutic regimes are looking for alternatives. There have been patients who have benefited a lot.

CHAIR: Senator Di Natale, do you want to finish up your questions?

Senator DI NATALE: Yes. I am interested in the pathways for GPs. You can get approval through the Special Access Scheme for individual patients or you can become an authorised prescriber for a specific product. To become an authorised prescriber, you need to submit an application for ethics approval. Is that correct?

Dr Bartone: You need to provide the application which has the appropriate information about your training expertise and also what you are looking to do and why specifically you are looking to utilise it.

Senator DI NATALE: Yes, and ultimately it needs an ethics committee's approval to do that. I am talking about the experience of some GPs. One in particular applied for ethics approval through the College of Physicians and the College of General Practitioners and was denied it but then applied to the National Institute of Integrative Medicine and is in the process of getting that approval. I am interested as to—and this is for Dr Nespolon and potentially for Dr Speakman, although I understand you do not speak for the College of Physicians—what the thinking is behind that. Why would the colleges not assess somebody's application for authorised prescriber status and refuse that ethics committee process?

Dr Nespolon: I would have to take that question on notice, because I do not have that sort of detail available. I think we would have to look into that particular case.

Senator DI NATALE: It is published in *The Monthly*. It is Dr Karen Hitchcock. It is in Lucy Haslam's submission. I am aware of this case and so I am interested as to why the college would not engage in an assessment of it. If you could take that on notice, that would be helpful. I do not know if you have anything to add, Dr Speakman.

Dr Speakman: I could not answer that question.

Senator DI NATALE: Okay. I am happy for that to be taken on notice. I think we are running out of time now, so I am happy to hand over.

CHAIR: We have enough time for you, Senator Bilyk, to ask your question.

Senator BILYK: This is to all of you: who do you actually think should be providing GPs with the resources on the legislative and clinical aspects of prescribing medical cannabis? Who do you think should be doing that? That is one of the problems we are hearing today. Medical practitioners and GPs do not know enough about it. Who should be doing that?

Dr Nespolon: It is like any medication. I think there are a variety of places where you can get information which is from the companies who are producing a product. Ideally there would be some independent advice from government. We do get that from the various medicinal cannabis state departments that provide information about that. But, again, at the end of the day, there's got to be that desire by a general practitioner to want to prescribe it. There are some, as we know, who are particularly enthusiastic, and there are groups of doctors who don't want to prescribe it and who probably won't ever want to prescribe it until there is a sufficiently strong evidence base for it.

Senator BILYK: There is a third group, and that's probably some of the GPs in Tasmania, who might want to prescribe it but aren't allowed to. Have you got any comment to make about that?

Dr Nespolon: At the end of the day, most patients will come to see their GPs first about medicinal cannabis. We find it odd, I guess would be the gentlest way that I could say it, being in Tasmania, that general practitioners aren't able to prescribe medicinal cannabis, given that GPs are able to prescribe it in every other state and territory in Australia.

Senator BILYK: Can I just ask if your organisation has had any discussions with the Tasmanian government in regard to that?

Dr Nespolon: At a federal GP college level, as far as I'm aware, we haven't. But it is certainly something we should be taking up at the local level and probably at the federal level as well.

Dr Bartone: If I could make some comments also: in regard to the differences from state to state, we don't need to remind ourselves that we live in a federation and that those laws vary. In particular, they have that extra layer of complexity between state and state, and federally. There are occasions where we, from the federal perspective, see those differences as being exploited to the detriment of patients, and there are opportunities for the reverse. I suppose this is the province of COAG, for the COAG health ministers, where this could be raised, in terms of unifying the process.

Senator BILYK: Like having a national, linking system, approach or framework.

Dr Bartone: On such a matter where there is clearly confusion and a lack of coordination, it would make a lot of sense if there was, at least, a nationally agreed approach. That's No. 1.

No. 2 is in terms of education. Let's remember what I've already said—that is, when a product comes to market there are multiple channels around education information and dissemination of that to the prescribing doctors. This is a situation where we've actually put the cart before the horse and created this problem, because of parliament's decision to allow appropriate prescribing to occur. Therefore, it's implicitly prudent that government do contribute significantly to assisting in that education to be provided. Government doesn't have to provide it directly. It can utilise the other channels and engage them, and provide the funding and resources to allow them to spread that education further. This problem is made because of the premature decision to allow the regulatory availability of medicinal cannabis.

Dr Speakman: Could I add to that. I think, traditionally, non-commercial entities will provide information and training when there's evidence about what to use a product for, how to use it and how to bring it out into general usage in the community. I think that's the gap here. For most institutions that might take up the role of trying to educate GPs or specialists who are going to prescribe medicinal cannabis, their evidence base to go out and say, 'We're going to run a seminar on this and explain how to use it,' doesn't sit there to the criteria that we use, usually, to do such education.

Senator BILYK: There's evidence from overseas though.

Dr Bartone: But let's be specific about that evidence. Some of that evidence is very small trials. We need to replicate that using the local products, the local sources and the local formulations. That evidence needs to be replicated and reproduced using the local supply channels. That's what these trials that are clearly going on at the moment are about. We would normally have had them as part of the information and delivery to the market of the options to the user. That's why there's usually a staged approach between a drug coming out, going to patent, getting out through clinical trials and phase testing and then being available for market use. There are many stages along that, and through those processes there is further and further dissemination of information through the appropriate channels. We've had the most strict and stringent approaches to safety for the Australian public when it comes to medicines. We should not deter ourselves or risk changes to that because of what we're dealing with—the emotional and community concerns about the availability of a compound which they believe, on a limited amount of evidence, to be efficacious in certain conditions. We need to have the same protocols and procedures that have kept us safe and protected for so long.

Senator DI NATALE: But, Dr Bartone, you've got a family whose child is having uncontrolled seizures and has been on every anti-epileptic drug known to man and suddenly has a significant improvement as a result of being prescribed medicinal cannabis. We've heard from Epilepsy Action Australia and we've heard from Multiple Sclerosis Australia, the organisation that represents patients. There's clearly a big demand from within the community, and GPs are feeling it. The tone I'm getting from you is that doctors should refuse to engage in prescribing it until we get clinical trials. But drug companies aren't stepping up and sponsoring many of these products through the established processes, so we're in a dilemma at the moment. I'm interested in what the AMA's position is. On one hand you're saying we need evidence, and then on the other hand you're saying we need more education. It sounds to me like a confused position.

Dr Bartone: It's not confused, Senator. Let me explain it a different way. The evidence is absolutely required. Whatever case or situation occurs in the long run, we need that evidence one way or the other, either to validate what we're doing or to actually signpost and say: 'You know what? There are some risks here; we need to reassess and go back to the drawing board.' Whatever the case may be, we need the evidence. We've always been about the evidence guiding us in terms of protocols, guidelines and procedures.

Senator DI NATALE: That might be up for debate.

CHAIR: We're going to have to wind up. Perhaps you'd take on notice to expand your answer further. Today we've heard a lot that the number of people that are able to go through the proper process is very small, but there is a huge number of people using—in some submissions people have called it black market, and today they've

been calling it green market. They're basically accessing illicit material. I'd be interested in what you think the way forward is, because people are using these substances. We've heard evidence today of the success of using them. What is your advice to us about how we handle that?

Dr Bartone: I'm happy to provide you an extensive and full reply to that question, noting that anecdotal evidence has never been what the scientific community would accept.

CHAIR: Coming from a scientific background myself, I hear what you're saying. But the fact is that in the community out there we have people that are accessing these substances. I am not a specialist in this area, but I would argue that they should be able to do that with a degree of safety. I understand you're arguing that that safety isn't there, but the fact is that they're doing it. For senators that need to be providing advice and making recommendations, I'd like to hear some more about what your advice is.

Dr Bartone: I'm only too happy to.

CHAIR: We've come to the end of our time. After running for a while, we're just on time, so I'm going to have to wind up this session. Thank you very much for your time today. Thank you, Dr Nespolon; I know it's trickier on the phone.

Dr Nespolon: It is.

CHAIR: There are QONs—sorry; that is parliamentary talk for questions on notice. Could you please provide those by 5 February. It's a very short time line. I don't know if you're going to be able to meet 5 February, but could you make every endeavour to do so, please.

BRIGHTHOPE, Professor Ian, Founding President, Australasian College of Nutritional and Environmental Medicine

NATION, Dr Tamara, General Practitioner, National Institute of Integrative Medicine

O'BRIEN, Professor Kylie, Member, Australasian College of Nutritional and Environmental Medicine

SALI, Professor Avni, Founding Director, National Institute of Integrative Medicine

SINCLAIR, Mr Justin, Research Fellow, National Institute of Complementary Medicine Health Research Institute

[14:20]

CHAIR: Welcome. I'm going to get straight into it, given the time. Thank you everybody for coming today, we really appreciate it. I know you've been sitting in the audience, so you'll know that we have lots of questions. I now invite you, Professor O'Brien, to make an opening statement, and then we'll go along the panel.

Prof. O'Brien: I think we're in an unusual situation in that *Cannabis sativa* is actually a herb, a plant, and yet in many ways it's being looked at and treated as a pharmaceutical. Of course, if it's a synthetic copy of the molecule of THC or CBD then I would argue that it is a pharmaceutical. So that's part of what I want to contextualise.

Now, cannabis is currently an unapproved good under our system at the moment, and one of my arguments is it's probably time to approve it. Because it's an unapproved good, it then triggers this process by which doctors have to either use SAS B or the authorised prescriber scheme in order to be able to actually prescribe it. The other issue is that cannabidiol, CBD, is contained in schedule 4 of the SUSMP if it has 98 per cent or more of CBD. THC is contained in schedule 8, which is for controlled drugs. Also, if less than 98 per cent of CBD is in a product, it's also considered schedule 8. So you could have 97 per cent of CBD and the other percentage made up by other non-psychoactive cannabinoids and it would still be a schedule 8 drug, so there's another problem.

To pick up on something that Professor Iain McGregor spoke about before, a WHO report in 2008 stated that CBD has been shown to be safe, of low toxicity and not addictive, so our argument is that CBD could be regulated as a complementary medicine. Australia has a very good system for regulating the quality and safety of complementary medicine, so CBD could be listed or assess listed or registered on the ARTG as any other herbal medicine is in this country. This would then open up access to patients, and it would also allow it to be prescribed by other qualified healthcare practitioners. This would be in line with the US, Canada and Europe, where CBD is openly available to purchase over the counter or, indeed, online.

Some of the arguments about removing CBD from schedule 4 in the past have been about its interactions and potential interactions with some anti-epileptic medications—not all. Indeed, in the literature there have been some patient reports of some clinical trials where they have. There have also been reports where the children have been able to knock back or reduce a lot of their anti-epileptic medications. CBD's not unusual. Other herbs interact with other pharmaceuticals—this is well known by herbalists, and it should be by doctors as well—so something like that could be handled with correct labelling, and you may even want to cap the dose. That's another possibility in terms of being able to regulate CBD, just to follow on from Professor McGregor.

The other point I want to bring up is to refute that there's been a lack of education. When I was Director of Education at the National Institute of Integrative Medicine in 2018 we set up the first course that received RACGP category 1 continuing professional development points. We ran two courses that year in collaboration with NICM and ACNEM. Last year, through Global Health Initiative Australia, which is a not-for-profit organisation, I ran another course supported by ACNEM, and that was focused on mental health, chronic pain and medicinal cannabis. These are clinician training events. They are two-day courses, and clinicians are taught how to prescribe. They're very strongly evidence based. If anyone's ever been through the RACGP approval process, they look at absolutely every slide. There was some pushback last year when I wanted to get the category 1 points. They said that there were too many slides and that it's controversial—

Senator DI NATALE: What is a category 1 point?

Prof. O'Brien: Category 1 points are the top RACGP points they can get. They get 40 points in one hit for doing an activity. There was some pushback, and they said that there were too many slides to do it in that amount of time—and I had submitted it well ahead of time—and that cannabis was controversial. I said, 'That's exactly why we should be bringing it out into the open in an open forum like this.' Anyway, they did approve it in the end. The work that we're doing continues in the education space. ACNEM is partnering with GHI Australia to run a

course in Brisbane. We're bringing out Dr Philip Blair, a retired colonel, from the US. We're also developing a suite of online courses that will be available for any healthcare practitioner to be able to do.

The third thing I want to bring up is to refute the idea that there is a lack of evidence around medicinal cannabis. The National Academies of Sciences, Engineering, and Medicine in the US put out a report in 2017—and there have been many studies since then—where they summarised randomised controlled trial data and systematic review data. They concluded that there was substantial or conclusive evidence that cannabis or cannabinoids were effective for chronic pain, spasticity associated with MS and chemo-induced nausea and vomiting, and they also found moderate evidence that they were effective for sleep disorders. That's only taking account of systematic reviews and RCT. There have been a lot of other studies since then. Professor McGregor also alluded to the fact that there are a lot of studies in the area of epilepsy as well as many others. So I would like to refute the idea that we have a lack of evidence. Not all clinical trials need to be done in Australia. I'll hand over to Avni.

Prof. Sali: Thank you for the opportunity to present. Just briefly, our institute is a charitable institution. It's academic. We have about 30 clinicians, most of them doctors. We do research and we're increasing our teaching. I see patients, and about three-quarters of them are cancer patients. I'd like to briefly describe a couple of them because they were very close to me: one of them was a sister-in-law and the other a nephew, both of whom died from cancer last year. They were having pain and they were having difficulty sleeping. They were on all sorts of opioids—there are usually two or three that many cancer patients are on—and not only were they not even controlling the symptoms; they were also causing significant side effects. Both of them eventually went on cannabis oil and both of them had remarkably good responses. That is not unusual in my clinical experience. Also, about one-quarter of the cancer patients that I see are already getting cannabis from some unregulated source, and that's another problem.

I got an email from the daughter of our former next-door neighbour on a farm at Shepparton. She's in a nursing home now. She's been a bit unwell. They've done a few investigations, but they couldn't really find out what's going on. She sent me the list of drugs that she's on. She's on about 15 drugs, which is not unusual for people in nursing homes. She basically sits in a chair, because there's nothing much you can do in a nursing home—I've been to that nursing home. For arthritis, she's on an opioid which she takes twice daily. She's having Celebrex, which is quite a dangerous anti-arthritis drug. I'm also wary of very large studies that aren't independent. They may be large, but are they independent? Who's paying for the result? COX-2 inhibitors were thought to be very safe, yet were proven to almost double stroke rates and heart attack rates. So she's on Celebrex as well and she's having the high dose of Panadol Osteo two or three times daily to control arthritis. In my substantial experience with arthritis, if you are just sitting in a chair the arthritis isn't causing much trouble, and cannabis may well be useful. I know from clinical experience of my own and of others that it can be useful in that situation, especially when you're looking at the three drugs that she's already on, which are dangerous and have major side effects.

CHAIR: Professor Brighthope, you came in late. You are with the institute as well?

Prof. Brighthope: Yes, I am. That's correct. I am the founder of ACNEM as well—40 years ago.

CHAIR: From the institute, do you or Dr Nation have anything you wanted to add?

Dr Nation: Just in brief, I'm a general practitioner as well and a member of the College of General Practitioners. I'm an authorised prescriber and I've also used the Special Access Scheme type B extensively. From patients' perspectives that I've seen at work, cost driving and access to doctors who are able and willing to prescribe has been a barrier. As a clinician, having undergone my medical training in Australia, I know that key barriers have been knowledge and education related to the endocannabinoid system and an understanding of how the TGA and the Special Access Scheme work, because this is quite distinct from the other pharmaceutical medications and lifestyle measures that we prescribe patients. On top of all of this, clinician attitude and the willingness to be taken along with a patient and give the patient time on their therapeutic journey have also been a barrier in a general practice setting, because most of the conditions are chronic and this is a complex area in medicine, so we need to give our patients time.

Prof. Brighthope: Can I just add that ACNEM, NIIM and NICM are the three organisations that started the education programs. The president of the AMA stated that it would be good for government to give support to education, and I'd just like to table that these organisations are the primary ones and the ones that I regard as the best in the country to continue medical education on this valuable herbal medicine.

Mr Sinclair: I appreciate the opportunity to speak to you today as a research fellow at NICM Health Research Institute at Western Sydney University, where I also coordinate the Australian Medicinal Cannabis Research and Education Collaboration. By way of background into NICM Health Research Institute's involvement and

capabilities in the emergent field of medicinal cannabis, our TGA certified labs conduct analytical characterisation of cannabis products for industry. We've been active in medicinal cannabis education events, as has been previously discussed, and currently have three medicinal cannabis clinical trials in development. This December past, we were awarded an Office of Drug Control manufacture licence, making our institute fully compliant with all state and federal regulations to pursue benchtop and clinical research with medicinal cannabis.

Our submission details a number of the barriers relating to patient access to legal medicinal cannabis in Australia, and has been based on communication with patients, advocates, medical practitioners and industry stakeholders as well as incorporating our own peer reviewed and, as yet, unpublished research. However, for timing I'll keep to three critical take-home points, which will likely result in greater patient safety and access, leading hopefully to improvement in overall patient care and quality of life for those seeking amelioration of symptoms and suffering with what is in Australia a medicine of last resort.

Firstly, cost has been consistently expressed by participants from our various research projects as a limiting factor to participation in the current legal scheme. This goes hand in hand with public safety. Considering that approximately 100,000 to 200,000 Australians are currently utilising cannabis illicitly for therapeutic purposes, inhibitory costs can potentially push legitimate patients out of a legal system under the care of a medical professional and towards possible harm.

Secondly, the lack of regulatory harmonisation across all states and territories regarding legal access pathways causes some patients great hardship in accessing what others in larger states can do more freely. This need for harmonisation also extends to the disparity of a legal patient being subjected to our current drug driving laws, which, at present, detect presence but not impairment and make legitimate patients not only feel like criminals but sometimes choose to forsake legal access altogether, due to driving being an important part of employment, family or their rural location.

Thirdly, the challenge of overcoming the pernicious effects of stigma cannot be overstated. Concern over ostracism or discrimination from religious groups, employers, community members, doctors and family for using medicinal cannabis has been identified in our ongoing research as a concerning barrier to access for what is once more a legal medicine in Australia. Funding for an accessible public education platform that addresses the safety and science around medicinal cannabis could go some way to mitigating this stigma. Whilst increasing numbers of Special Access Scheme category B application approvals by the TGA are certainly encouraging, addressing these aforementioned barriers will likely see approvals grow far higher and faster, providing an opportunity for those who have not found relief from current medical treatment.

Thank you once again for the opportunity for contribute to the inquiry. I look forward to addressing any questions the committee might have.

CHAIR: Thank you.

Senator DI NATALE: Can I go to the question of evidence that you brought up at the start of the conversation. There's clearly a difference of views between the AMA position and your position. Their position seems to be that there are two issues: doctors being educated and question marks about the evidence. You expressed a strong view that there's good evidence for a number of conditions. Why the disagreement?

Prof. O'Brien: I've been reading the literature nearly every day for the last two years. I'm writing a book on it at the moment that's contracted to Springer, a medical book company in the US. I'm focusing on mental health in particular, because that's one of the highest reasons that people self-medicate. It's chronic pain, then mental health—things like PTSD. I've read a lot of the literature and, along with Justin, Ian and Avni, I've been involved in creating the doctor education for the last couple of years as well. I've had to understand the evidence about the endocannabinoid system and how medicinal cannabis and the various parts of it work. I don't know how much reading they've done, so I can't comment on that, but it may simply be lack of knowledge because they haven't been into the literature as much as people like Ian, Jonathon, Justin, et cetera.

Senator DI NATALE: It's obviously an emerging area of work. Is there any training at an undergraduate level around the endocannabinoid system? I remember that, when I went through it, all I was told was that it was bad for you and to stay away from it. We didn't even know that there was such a thing as the endocannabinoid system.

Prof. O'Brien: I can't comment, because I'm no longer involved in the university sector myself. Justin might be able to talk to this. Certainly in the US, there is now teaching about the endocannabinoid system and cannabinoids in several medical curricula. I'm not aware of it here, simply because I'm not involved in it. Justin, are you able to talk to that?

Mr Sinclair: To answer your question, Senator, I gave a talk at a hospital in Queensland late last year where I asked everyone in attendance—some 130 nurses, doctors, et cetera—whether they had had any training in the

endocannabinoid system during their undergraduate training, and not one hand was raised. As you rightly said, the only thing that many doctors have learned in their undergraduate training is that it's a social drug and it has problems with addiction or abuse. They have potentially learnt nothing about not only the therapeutic benefit of cannabis but also the endocannabinoid system. To say that this is emerging evidence is challenging, because we've known about the endocannabinoid system since the 1990s. It's now 2020. I understand that medicine can be a conservative profession, but that's a fair amount of time. It should be being implemented; I know that it is in some pharmacy undergraduate programs. I'm not aware of any medical faculties in Australia that have it as a substantial section in their curricula at the moment.

Senator DI NATALE: On the question of education, obviously GPs are struggling to know where to go for good information. I imagine that a lot of the people who are sponsoring some of these products don't have the budgets to provide the dinners that maybe some of the big pharmaceutical companies do. I note, firstly, that the AMA and the College of General Practitioners didn't refer to your training program when I asked them, so that's a surprise to me. And I've heard of this second-hand. This seems to be probably the most structured teaching around medicinal cannabis available for GPs—would that be a fair thing to say?

Prof. O'Brien: Yes, I'd say that's fair.

Senator DI NATALE: How long does the course run for?

Prof. O'Brien: It's a two-day course, from nine to 5.30 each day, and it's pretty well packed.

Senator DI NATALE: And you do it twice a year?

Prof. O'Brien: Twice a year at the moment, and that's really just because we're all not-for-profit organisations, so we don't have any government backing on this, so we actually rely on sponsorship from some of the medicinal cannabis companies, and nutritional medicine companies as well, to be able to run these things. We're bringing out specialist doctors in cannabinoid medicine from the US. So we do rely on that to be able to run these things.

Senator DI NATALE: What's the cost to a GP to attend the training?

Prof. O'Brien: Eight hundred dollars for a two-day training course.

Senator DI NATALE: There you go. There's a good reason why a lot of GPs will stay away: \$800 for the two days.

Prof. O'Brien: That's actually on par with most two-day conferences. We did a bit of a benchmark before we set that.

Senator DI NATALE: Sure, but it's a bit different from going to a dinner at a restaurant for nothing.

Prof. O'Brien: Exactly. But this is—

Senator BILYK: How many people have you trained so far?

Prof. O'Brien: In 2018 I think we had about 55 at the first one, 53 at the second one—around that. We had a couple of pharmacists in there and a couple of herbal medicine practitioners as well. At the one that we ran last year we probably had about 50. We split it into a one-day conference, to which, basically, anyone could come along, and then the next day was the masterclass. So we probably had around 24 or 25 to the masterclass the following day and around 50 to the conference the day before. They're not huge numbers. They're not bad, but they're not huge.

Senator DI NATALE: What about if you wanted to access the information and you just didn't have the two days to devote to it? I imagine that's probably a big part for a lot of GPs.

Prof. O'Brien: Of course.

Senator DI NATALE: What are the other options?

Prof. O'Brien: At the moment, there are a few online courses that you can access via the US, but they're fairly clunky. There are people just reading out their PowerPoint slides. At the moment I'm working with ACNEM to develop online modules. These will be short bites of information, 20 to 30 minutes maximum. You can just learn about the endocannabinoid system, or you can learn about: 'What's the evidence around anxiety and medicinal cannabis?' That's actually work in process right now.

Senator DI NATALE: On that question of ethics approval, there are two different pathways as a GP. One is that you can get special access for one patient; the other option is that you become an authorised prescriber where you can prescribe one product to whoever comes through the door if they qualify for it. To become an authorised prescriber you need to go through an ethics committee approval process; is that right?

Prof. O'Brien: Yes—or a specialist college. So any of the colleges could actually have this process. But, at the time, two years ago, Professor Brighthope came to me with a problem and said: 'There's really no way that GPs and other doctors can be approved to go through to the TGA.' The TGA is the final approval source, but before then—

Senator DI NATALE: Sorry, you'll have to walk me through this.

Prof. O'Brien: I will walk you through it, yes.

Senator DI NATALE: So when you say they're 'the final approval source', you mean—

Prof. O'Brien: They give the final approval for a doctor to become an authorised prescriber, but it's a two-step process. You first have to go through either an ethics committee or a specialist college to get approval, and, if you get approval, you take that letter and you apply to the TGA and they give the final approval. At the time, there were no ethics committees in the country that we were aware of that were actually approving applications, and, as far as we were aware, specialist colleges weren't doing it either. So I happened to be chairing the NIIM ethics committee at the time, and we set up the process. We have a policy, procedures and application form. We tested it out with the first one. We brought experienced doctors onto the ethics committee. It was already a properly constituted, NHMRC approved committee, and we brought extra doctors onto it so that they could be present to assess the applications. Since then, I think—Avni, you might be able to give them the exact figures—it's probably been over 30 doctors that have gone through that authorised prescriber process. So you're correct in that, once you're approved for a particular condition—and it's also tagged to a particular product, so you nominate the products. The problem is, though, if you decide that there are some new products on the market and you want to be approved to use those, you've got to go back through the ethics committee and off to the TGA again. So that's a barrier. If you decide, 'Look, I've been approved for chronic pain, but actually I'm seeing a lot more people with anxiety,' then you have to go through the process again. This is unusual in that this is not expected of any other medication in the country.

Senator DI NATALE: Just to follow on from that: in the application process, are you the only medical college that will sign off on authorised prescriber status or have people go through that process? Are there any other colleges?

Prof. O'Brien: I'm not aware of any other medical colleges.

Senator DI NATALE: It is something we might put to the TGA later on. As a GP, how do I become an authorised prescriber? Is it only through your college?

Prof. O'Brien: As far as I'm aware, we are the only one that has that process set up.

Prof. Sali: It's very difficult for someone outside Melbourne or interstate.

Senator DI NATALE: Yes.

Prof. Sali: The other problem is that, when I talk to GPs, they're not even interested in being educated, because they hear about how difficult it is to prescribe.

Senator DI NATALE: Yes.

Prof. Sali: GPs didn't even like to ring the health department to get an authority okayed, let alone fill in forms and go to ethics committees and everything. So, if you want to turn anyone off from wanting to be educated in this area or to prescribe in this area, you have the current system.

Senator DI NATALE: So it's not necessarily that they're not interested in the medicine; they're not interested in the bureaucracy around the medicine.

Prof. Sali: That's right.

Senator URQUHART: Just leading on from that, I want to get your view—and I open this up to the panel. What do you think about the SAS B and AP access pathways? Are they unnecessary? How should access be regulated?

Dr Nation: I'm happy to speak to that. I think that, as an initial pathway or as an initial process, it has been great. I had to educate myself, as a GP who was naive about medicinal cannabis, to learn quite deeply about it, and having those pathways, which required a level of rigour and responsibility at state and federal levels, was excellent. All the studies were provided. You asked earlier about whether there is literature to support a particular product for a particular condition. Yes, there is. It's actually on the government website. Every single time you put in an application, you need an understanding of the evidence behind it. As a medical practitioner, you need to stand behind that, because you're putting your patient at risk in terms of a therapeutic trial.

Secondly, having done 50 to 100 applications and multiple authorised prescriber applications raises the question: do you still need to go through this ongoing process individual by individual, or could there be, after attaining a certain number of applications which have been approved, a different pathway? It would be interesting to see how the TGA and the government respond to that question.

Senator URQUHART: Yes, okay. Are there any other contributions?

Prof. O'Brien: I'd like to just reiterate what I was talking about before: the only reason that we have the SAS B and A for the authorised prescriber scheme is that it's an unapproved good. We're five years down the track. It's time to approve it. If you didn't have, as I said, CBD as a schedule 4 drug and it were regulated as a herbal medicine, which it is, then you wouldn't need to go through this authorised prescriber or SAS B process.

Prof. Brighthope: I tend to agree. There are five million Australians suffering from chronic pain. They're on multiple medications. Many of them are invalids and don't have a voice. I personally have gone through that experience. I believe we can use medicinal cannabis safely and effectively, because up until 1937 it was available to doctors to prescribe. It was a safe and effective herbal medicine, not medical cannabis. It's made as a herbal medicine is made. We can standardise the ingredients. It took me one hour to teach the first doctor who got their approved prescriber status how to prescribe it. It's very simple and effective to use. We have turned a very, very simple herbal medicine—with side effects if used improperly—into something that's become so complex that those suffering are going to continue suffering.

I know how we can bring best-quality cannabis medicine to the market, because I am involved in the market, I'm involved in education and research and I'm also a patient. So I'm pleading that the government do something to reduce the difficulty in prescribing. In Canada, for example, the doctors have had access to cannabis for 19 years. Most doctors in Canada will tell their patient: 'I want you to go on medicinal cannabis. Go across to the dispensary or see my nurse and she will tell you all about it.'

We have turned something that's basic and very simple to understand into something that's very, very complex. I take my hat off to the researchers, because I do want to see a lot more research being done. I have followed this for 10 years in the US. Olivia Newton-John and her husband are very good friends of mine. Her husband makes the medicine for her. I don't want to go down that track here. We have the TGA here—again, one of the most rigorous regulators in the world. That's why our complementary medicines are so praised—because they are manufactured under international pharmaceutical standards. We can do the same with medicinal cannabis.

Senator URQUHART: Turning to CBD preparations with low or no THC, should they be regulated as herbal medicine?

Prof. Brighthope: I believe so, but I think that's a long bow that we are pulling at the moment.

Senator URQUHART: Why is it a long bow?

Prof. Brighthope: Why? Because there's so much opposition. Any politician who recommended that would have to be extremely courageous. However, as a doctor, I do recommend it.

Senator URQUHART: But if there is no THC in it—

Prof. Brighthope: There's no THC.

Senator URQUHART: Then why is it—

Prof. Brighthope: It's not a problem. You can go anywhere in the States and pick up CBD and you can virtually go anywhere in Europe and pick it up.

Senator URQUHART: So is the opposition about people not understanding the use?

Prof. Brighthope: Yes.

Senator URQUHART: So it is the educative—

Prof. Brighthope: Yes. It's not a drug. Take grapes: they are healthy and you eat grapes but, when you turn grapes into alcohol, they become something that could potentially be very toxic. The ratio between intake, safety and toxicity with regard to cannabis is that you would have to smoke something like 100,000 weed to get to a toxic level of THC. You'd be sick before you get anywhere near 10. I am being a little light hearted here, but, without the THC, CBD and we believe the other cannabinoids, CBG, CBA, CBD et cetera—there are a whole range of them but the two that are studied the most are CBD and THC—the decarboxylated, or non-acidic, form doesn't have the psychotoxic effect.

Certainly with CBD, you have a psychoactive effect, but that is a beneficial effect—it relieves your anxiety and depression. And I can tell you, from a company that is actually providing it for pain, the next most common is anxiety and autism. Parents have been using it illegally for autism and for epilepsy for a long time, and now they

are starting to get the real stuff for their autistic children. Do you think somebody wanting to treat their child would spend \$300 a week on a bottle of oil if it wasn't helping them? Anecdotally, yes, but thousands of anecdotes have to mean something—honestly.

Senator URQUHART: Mr Sinclair, you talked about your research that's not published. What is the time frame for that?

Mr Sinclair: We are hoping to have the focus group research that we are currently undergoing published by the end of this year. Research that we published late last year was around endometriosis. We identified that around one in 10 women with endometriosis are using cannabis illicitly to manage their pain and associated symptoms. It was the highest-ranked self-management strategy for pain. Fifty-six per cent of that cohort were able to reduce their pharmaceutical medications by 50 per cent or more. It also assisted with anxiety, depression, sleep, nausea and vomiting. That's the reality in a chronic pain condition such as endometriosis.

Endometriosis affects an estimated 740,000 Australian women, but there is a cohort of women who have a very severe presentation of the disease for which current medical therapy isn't working, and they are resorting, already in this country, to utilising that. We are happy to hear that there have been approvals through the TGA system for chronic pain associated with endometriosis, which is great. But the research that we have done showed that they were spending on average \$100 per month—whereas \$250 to \$350. It's a pretty concerning thing that they raise consistently.

CHAIR: As there are no other questions, thank you very much for your time today. It's very much appreciated.

JACKSON, Mr John, President, Victorian Branch, Pharmaceutical Society of Australia

McMAUGH, Mr Jarrod, Project Pharmacist, Pharmaceutical Society of Australia

TASSONE, Mr Anthony, National Councillor, Pharmacy Guild of Australia

[14:55]

CHAIR: Welcome. Do you have any comments to make on the capacity in which you appear?

Mr Tassone: I'm a community pharmacist and the Victorian branch president of the Pharmacy Guild of Australia. I pass on the apologies of our national president, George Tambassis, who unfortunately is unable to be here today.

CHAIR: I invite the Pharmaceutical Society to make an opening statement.

Mr Jackson: The Pharmaceutical Society of Australia—PSA, as I'll refer to it—is the only Australian-government-recognised peak national professional pharmacy organisation, representing all of Australia's 31,000 pharmacists working in all sectors and across all locations. PSA has a strong and engaged membership base that provides high-quality health care and shares custodianship of safe and effective medicine use with the Australian community. Pharmacists practise under a rigorous and robust professional and ethical framework. The care, wellbeing and safety of patients are at the centre of all aspects of pharmacists' practice. In addition to providing a safe, accessible and timely supply of medicines, pharmacists assist by responding to queries from patients and prescribers about processes for providing clinical and medicines information.

The submission that PSA lodged to this inquiry was informed largely by the PSA membership, who have experience in sourcing and supplying medicinal cannabis products to patients and supporting patients and carers in navigating through the processes and arrangements. As it does with all therapeutic products, pharmacists have an important and integral role in supporting patients and carers in the supply, use and management of cannabis products for medicinal purposes. From the perspective of pharmacists, significant challenges have been and continue to be experienced by patients, carers and health professionals. In relation to this inquiry, based on the observations and experience of pharmacists, PSA has focused on the following four issues: the application approval issues for patients, access issues for pharmacists, professional support for pharmacists and national consistency in regulation. I would like to speak to each of these in turn.

With regard to application approval issues for patients, PSA acknowledges the work of the Commonwealth, state and territory governments in implementing arrangements for cannabis to be accessible for medicinal use. Unfortunately, the majority feedback from pharmacists is that patients are often confused about the process and frustrated with the delays they experience in waiting for their applications to be approved and the medicines to be received. This is compounded by occasions when products are out of stock and the approval process needs to be repeated. Pharmacists are aware that the lengthy processes and uncertainties about the approval of applications often leave patients feeling stressed and anxious—and this can impact on their health and wellbeing—as well as being aware of the stress and burden felt by families and carers. Pharmacists are also aware that the financial impact on the patient is often compounded by the fact that they are only able to work part time or are unable to work at all due to their state of health and the requirements of treatment. Some pharmacists have reported a patient is continuing to or is reverting back to sourcing their cannabis via unregulated channels as they feel the current arrangements are so unwieldy and burdensome that they are willing to take the risk of breaking the law. Thus, overall, pharmacists do not regard the current arrangements to be adequate in providing timely equity of access for patients.

The second point I want to speak to is access issues for pharmacists. As the conduit between the prescriber and the patient, pharmacists are called upon to resolve problems regarding access to supplies of medicinal cannabis. Pharmacists who have been engaged in the supply of medicinal cannabis products for patients have reported on complex and cumbersome arrangements, inefficient processes, time-consuming steps and delays in product procurement, and substantial costs to patients and the pharmacy business. I'm sure Anthony Tassone will make more comment on this shortly.

The third point I want to raise is professional support for pharmacists. I appreciate the terms of reference refer to support for prescribers, but we believe there's a sound argument for providing support for pharmacists as well. In addition to responding to queries about application approvals and access agreement arrangements, pharmacists assist by providing clinical and medicinal information. Given these roles in assisting patients, carers and prescribers in the supply and use of medicinal cannabis products, pharmacists must be supported and resourced with clinical information, practice support resources and updates of any new information, access arrangements or evidence base of therapies. Pharmacists have reflected that there is limited availability to easily access concise

information about medicinal cannabis products. Pharmacists have also reported that available clinical information about medicinal cannabis products is not necessarily tailored in the most useful or appropriate way for pharmacists. The PSA would welcome the opportunity to work with governments and other stakeholders to increase the scope and coordination of resources and reach of information to health professionals as well as patients and carers.

The final point I'd like to make in this opening statement is in relation to national consistency. Australia has adopted a successful and globally recognised national approach to medicine approval, access and funding. While recognising jurisdictional sovereignty, the PSA would support efforts to establish national consistency in medicinal cannabis access provisions. Finally, the PSA believes it is in the long-term interests of Australian patients that governments continue to invest in research and trials and work with health professionals and patients to improve access arrangements. On behalf of the Pharmaceutical Society, I'd like to thank the committee for the opportunity to contribute at this stage.

CHAIR: Thank you. Before I move on, Mr McMaugh, do you want to add anything?

Mr McMaugh: No, not at this point. I can answer questions, but I don't need to add.

CHAIR: Mr Tassone.

Mr Tassone: Good afternoon and thank you for the opportunity to address the committee on this matter. The Pharmacy Guild of Australia, as you would be aware, is the national organisation representing community pharmacy. We have a keen interest in ensuring that products available in the Australian market meet high quality and safety standards and have a proven record of efficacy when it comes to medicinal cannabis. Therefore, we believe that a suitable and efficient regulatory framework must be in place to ensure these objectives are met. As stated in our submission, we support the medicinal use of cannabis preparations following appropriate consideration and assessment. To that end, we believe the Therapeutic Goods Administration, the TGA, as the existing regulatory body, is the most appropriate framework for this to occur, and therefore do not believe that the creation of a new separate regulator to oversee the medicinal cannabis supply chain is required. We also believe that the Pharmaceutical Benefits Scheme, the PBS, is the appropriate system to subsidise access to pharmaceuticals in Australia. The main reasons for our position on this include that changes to the regulation of medicinal cannabis have the potential to fragment the regulation of medicines in Australia as well as lead to confusion. To ensure adherence to the Australian national medicines policy and specifically the quality use of medicines, medicinal cannabis should be regulated in the same manner as every other therapeutic product registered with the TGA.

The TGA possess the necessary experience and expertise to regulate medicinal cannabis products and have already registered cannabis based products such as Sativex, or nabiximols. The TGA have the ability to test and certify products and have the powers to refer to the ACCC, if required, any matters of pricing or advertising standards. The TGA also have the ability to track importers and distribution. They have the ability to manage adverse events and take appropriate action where necessary. There should be clear and consistent channels-of-communication protocols in the event of safety alerts and consumer-level recalls of these products. Again, the TGA have the ability to manage these as part of their function.

We also believe that it is entirely appropriate for the PBS to be used for subsidising patient access to medicinal cannabis products and that it would be unnecessary and wasteful to develop another subsidy scheme along with all the attendant bureaucracy and additional costs of evaluation, listing and claiming processes and whatnot for medicinal cannabis products via a different pathway.

In relation to training and support that might be required to support a good network of community pharmacies to become involved, we believe that there is a need to improve the knowledge and skills of all health professionals, including pharmacists, relating to cannabis regulation, clinical interactions and indications and the use of medicinal cannabis. The guild has always supported programs that enhance the capacity of health professionals to undertake effective intervention and support for clients with conditions that are resistant to the most commonly used medicines and interventions, such as treatment-resistant epilepsy in children, multiple sclerosis, cancer and severe neuropathic or arthritic pain.

There are some other matters from a patient perspective that the Pharmacy Guild have some concerns about in relation to current experiences with medicinal cannabis products that our members have fed back to the Pharmacy Guild that may not have been included in our initial submission. There is no requirement for a consumer medicines information, or CMI, leaflet to be provided under the SAS B or Special Access Scheme drug class. This is not in the interests of patients, as it should be mandatory for medicinal cannabis products to provide such a

resource. There are some examples where sponsors have provided a similar type of resource for their product, but we would like to see this across the board for medicinal cannabis products.

Under the SAS B classification, doctors would be able to prescribe and dispense medications for patients themselves. We do not feel, for medication such as medicinal cannabis, that it is in the interests of patients if their regular GP or community pharmacy are bypassed in the delivery of treatment with no visibility in their patient care. This could potentially lead to insufficient checks against other medications taken for conditions diagnosed in patients. Currently there is actually no standard coding for these products for prescribing and dispensing software platforms for doctors and pharmacists. This can actually add complexity for doctors prescribing and pharmacies dispensing these products compared to other prescription medicines. Due to the lack of standardised coding for these products, there may be undetected interactions on databases that assess contraindications with other medicines or conditions and potential issues in uploading to centralised databases such as the My Health Records. Having such standardised coding for medicinal cannabis products will again improve patient safety and the confidence of prescribers and pharmacists in these medicines.

Unlike other prescribed medicines, there is a lack of guidance from manufacturers on a milligram or per-unit basis on the THC or cannabinoid levels of their products on the packaging. This can lead to patients having a product prescribed and dispensed without such information that you would expect on a medicine for their treatment.

I would also like to mention briefly some potential barriers to participation from a community pharmacy standpoint. Some of our members have contacted the guild to inform us of some sponsors of medicinal cannabis products informing doctors and patients that their products will be supplied from community pharmacies at a particular price without any agreement from or warning to the pharmacies. And they have little if any margin that recognises the pharmacies' involvement through administration, storage, dispensing and counselling patients for these, in some cases, schedule 8 medicines. We believe that these manufacturers are trading on the goodwill of community pharmacies and expecting them to, in some cases, dispense in a way that barely covers their costs.

As you would be aware, prescription medicines are not ordinary items of commerce, and pharmacists should not be put upon by manufacturers and be expected to dispense and counsel patients on medicinal cannabis products for little or no reimbursement. Additional costs could also be a barrier for some pharmacies as some medicinal cannabis products may need to be temperature controlled, which would require these products to be stored separately in a secure refrigerator as required by state and territory legislation.

If no TGA registered products are available through standard supply chains—for example, our existing wholesalers—sourcing cannabis directly from suppliers could also prove difficult and costly, as has already been pointed out by the Pharmaceutical Society. As mentioned earlier, some sponsors of products are advertising products to medical practitioners with a dispense price to patients and consumers that does not include any reimbursement, or little margin, for pharmacists to cover the cost of stocking and dispensing these products. This puts pharmacists in the invidious position of telling their loyal patients that they must charge a higher price than they are expecting or dispense at a price that barely covers their costs. I am happy to expand on the issues raised. Thank you again for the opportunity to present today.

Senator URQUHART: I want to follow up on a comment that Mr Jackson made. You talked about a product being out of stock and the process having to be repeated. Is that the process of the forms and the applications?

Mr Jackson: The application processes do vary from state to state. It can arise on occasion that, if an application has been processed and access to the product is not readily available, a new application may well need to be initiated.

Senator BILYK: Is that because the process is for an individual drug, not a class of drugs?

Mr Jackson: That would be one of the contributing factors.

Senator BILYK: We often hear that medicinal cannabis should be used as a last-line therapy or a medicine of last resort—and to me that implies near death, to be honest, or that there is no other drug that is suitable for the patient—but then we're hearing that there are hiccups, delays, confusion, lack of access and everything else. If you had to give us a short, one-line statement about what should happen, what would it be? What is the critical thing we need to do? Mr Jackson, you mentioned trying to move to a national framework to—

Mr Jackson: I think the answer behind your question is the definition of what we mean by 'medicinal cannabis'. We are used to working with products that, by their nature, are standardised and able to be replicated, and consequently can be registered. The definition of medicinal cannabis arose in terms of a therapeutic use, without being clear as to exactly what the product would be. Personally, I perceive that with the passage of time a number of the cannabinoids that either are synthetic or have been extracted in a standardised format will easily fit

into TGA regulation and, if evidence is there, potentially into PBS funding. Consequently, the processes for timely access would be resolved. But with our definition of medicinal cannabis also capturing non-standardised extracts it makes it nigh impossible for the TGA to use its standard processes, and consequently we have the inquiry, basically, or the confusion in the community, and a lot of the difficulties in access.

One of the access pathways is, of course, through SAS. One of the SAS conditions is imminent death, but that's not always the case with the need for cannabis. I agree with you that it's generally thought of as 'after other more evidence based therapies have been tested' but that doesn't mean the person is necessarily near death. They may well be chronically afflicted and have used and exhausted all other options but not necessarily at that stage where you could classify them, to satisfy SAS access, as near death, but there would still be a desire to use cannabis.

Senator BILYK: In that respect, should people have to go through the process of trying everything else if their personal choice is to access medicinal cannabis? To me it seems that somebody out there's saying, 'You have to try all of these other things, no matter what you and your GP think would be right, and basically be a guinea pig.'

Mr Jackson: It does warrant reflecting on what's happened in some other countries, in this regard. The Canadians established a process for approval of medicinal cannabis, which was very specific—particular prescribers and particular clinical indications—and carried such conditions, as you mentioned, after other therapies had been used. They moved quickly to the point where, basically, any prescriber could initiate supply for any indication they thought fit. But that was supported by a standardised supply process by the Canadian government.

I think we actually have two issues here. One is the approval process, which has all the difficulties of knowing exactly what it is we're talking about. The other one is the approval-of-supply process, which is complicated by the fact that some of these are not standardised products.

Senator BILYK: Does anybody else want to make a comment?

Mr McMaugh: With regard to the evidence around medicinal cannabis, we're stuck in a bit of a catch 22 in that evidence is generated through commerce—the more something is used, the more capacity you have to get the evidence for that product. Yet we're in a situation where, potentially, the biggest market in the world for pharmaceuticals doesn't use medicinal cannabis the way we do in Australia. It has dispensaries that provide products that are made locally—or they're not medicinally based, let's say. We have a situation where people won't want to use a product that they think doesn't have evidence—even if there may be evidence existing—until it's the last resort, whether that's appropriate or not. We're not going to have in Australia the level of use of these kinds of medicines that would generate the kind of evidence that you need.

So far the government has funded the resources for manufacturers and growers, but it really should consider a quite strong investment in evidence generation and validation to ensure that the use of those medicines for Australian citizens is backed by the kind of evidence that people are asking for. There is evidence out there, and you can challenge any level of evidence. It needs to get to a level of evidence where people are categorically able to say, 'This is a medicine that we should be using in these situations, not as a last resort,' and the clinician has the choice to use that medicine based on their insight into their client and on their expertise, rather than government saying, 'You must not use this until it's the last resort.'

Mr Tassone: I support all the comments that have been made in response to the senator's question and the question around delays in access for patients. At each point in the doctor's consultation with the patient and in the consideration, the prescribing, the patient going to the pharmacy, the pharmacy trying to source the product on behalf of the patient, there's a slightly different approach that needs to be taken compared to what we're traditionally encountering. Each step, if it's requiring something different or more time, can all build up for patients: if doctors have less certainty as to what they're actually prescribing—and there's a need for education and professional development there—if, when they're prescribing something on their software platforms, it isn't listed or standardised as it is to check if it's safe and appropriate compared to their full medical history; if that's also the case at the pharmacy level; and the pharmacy level having to deal with a multitude of different suppliers, all with different terms of arrangement, rather than our traditional wholesalers that are what we call full line that have the full gamut of Pharmaceutical Benefits Scheme items. Each step in the process adds time. The patient is bearing that brunt at the end of it, and it is causing uncertainty and frustration for clinicians all along the way.

Mr Jackson: Laid over the top of that, if I may, is the medicolegal responsibility of both the prescriber and the pharmacist. The less evidence you have for the efficacy, including the safety of the product, the more difficult the position that you find yourself in.

Senator URQUHART: Can I just comment there. Mr McMaugh, I think you said that there's not been a lot of evidence generated because of the process—the fact that it's not readily available.

Mr McMaugh: That's what you get from most commercial products, because that market—that is, the USA—doesn't exist the way it does for other medicines.

Senator URQUHART: But isn't this a medicine that's been used for a very long time around the world? Is there not evidence that we can use internationally to help support us in—

Mr McMaugh: The use of medicinal cannabis has existed longer than the format of gathering evidence that we currently use. That means that a lot of that use existed in a time when we didn't gather evidence around it. You talked about anecdotal use. Anecdotal use that says, 'This person had this experience,' is completely valid, but you can't necessarily translate that to the next person or the next. Yes, this person is getting their benefit, but we don't know that that's going to happen for the next person. So gathering the evidence needs to take into account not only small-scale studies that find where it's going to be useful and where it might not be useful but also the risks associated with it. If we look at a million people using a blood pressure medicine, we can detect those very rare side effects that might only occur when you've got that many people involved, and we don't have that level of evidence around medicinal cannabis. That doesn't mean that there's no evidence; it just means that the level of evidence that we're relying on is different from what we're used to with other commercial medicines.

Senator URQUHART: Right.

Senator BILYK: I want to ask about something that hasn't really come up today so far. One of your submissions—I think it was the Pharmaceutical Society's—talking about a pharmacist's experience with the procurement of a particular medicinal cannabis product, said:

Patients are required to supply personal details to a commercial third-party prior to supply from the distributor to the pharmacy. This process ... increases the risk of breaching patient privacy.

Can you talk us through that and clarify for me what that means.

Mr Jackson: The supply arrangements are emerging. As we have new companies and new registrations occurring, supply arrangements are emerging, and there have been cases reported to us of patient information having to be provided back to the supplier to gain approval for that product to be provided through the pharmacy.

Senator BILYK: Even though the TGA had approved that for the patient? It's in box 3 on page 6.

Mr McMaugh: Yes, it's a requirement beyond what we would expect for other medicines. We don't supply details of patients to international companies or to Australian companies that manufacture standard pharmaceuticals. Because we're operating in—

Senator BILYK: Because this is specific?

Mr McMaugh: Yes.

Senator BILYK: It talks about 'the supply of product X'.

Mr Jackson: We can provide that information, if you would like, about what that product was. We weren't prepared to put it into the submission.

Senator DI NATALE: But the manufacturer had requested that information?

Mr Jackson: Correct.

Senator DI NATALE: Aren't there privacy implications here?

Senator BILYK: That's exactly my point, Senator Di Natale.

Mr McMaugh: Yes, there are.

CHAIR: We'll be asking the TGA. If you could provide as much information as possible—

Mr Jackson: We'll do that.

CHAIR: but I suggest we also raise it with TGA.

Senator DI NATALE: Just extending that question, you raised the issue of the arrangements for pharmacists accessing the drug being, I think, burdensome or cumbersome. What are some of the actual problems that you're encountering? That's one, obviously—people requiring patient information. That's obviously a concern. What are some of the other issues?

Mr Jackson: As soon as there's a higher level of regulation over any drug, it's a more burdensome process, and there is a higher level of regulation here because we need to ensure that the approval has been given, and the approval comes through with both federal and state aspects to it. So that adds to the burdensome nature of it. Then you get the situation where, the less frequently the item is used, the less familiar people are with it and so it

creates—perhaps 'burdensome' is not the right word—a degree of difficulty in arranging the supply. If you actually haven't accessed it previously, you've got to build those supply arrangements. You've got to contact the supplier, confirm there are supply arrangements, and there may well be account processes you've got to set up. So those two things add to that.

Senator DI NATALE: Yes. As a snapshot, would most pharmacies have one or two patients, or dozens of patients? Would many have no patients? I'm just interested to know what the impact is.

Mr Tassone: I have none. Jarrod might have more to add on that. But, from our feedback and experience, it can vary. It can vary depending on the prescribers in the area. But there are an increasing number of pharmacies and members of ours who do have patients that have been prescribed this. And then, as John alluded to, you might need to open up an account with each individual organisation and company. They will have their own different burdens of proof for that, different terms of trade, but then also different levels of service and timely delivery of goods. Whilst this sounds operational and not very exciting, probably, from this Senate committee's perspective—

CHAIR: We find this sort of thing very exciting!

Mr Tassone: I'm pleased!—it all adds to and contributes to patient access. And it is a deviation from what we're accustomed to dealing with. Whilst the number of patients and the number of pharmacists dealing with it can vary, Senator Di Natale, we know it's on the increase. We know that.

Senator DI NATALE: Yes.

Mr McMaugh: Can I comment on that?

Senator DI NATALE: Yes.

Mr McMaugh: This is from personal experience. I owned a pharmacy that compounded and I would receive prescriptions that would just say, for instance, 'medicinal cannabis, please compound' and no further details. That's an example of prescribers not knowing where to get access to the information; they're just confused by what's out there. With regard to whether pharmacies have many patients, you would find that pharmacies that are seeing clients who are receiving this medicine would probably gather a population of them because, if they've got that practice in place, people will know that and they will see them. Patient support groups will quickly identify which pharmacies have been able to put that in place. I had a number of patients come to me with prescriptions and SAS B forms, and when we told them what the price would be they just dropped it. I had a number of people approach me for it and never dispensed one.

Senator DI NATALE: That's interesting. As a pharmacist, if you wanted to get access to information, is there any structured training? I note that the PSA's got an online resource—I'll come to that in a minute. Where do you get your information from?

Mr Jackson: The Pharmaceutical Society has attempted to do it through a number of ways—presentations at conferences and online training, as you've said. But, of course, one of the biggest sources of information in this space is from the companies themselves, which carries certain issues. We have made the argument that there is a need for a much more rigorous level of information made available in a useful manner.

Senator DI NATALE: But it's pretty ad hoc at the moment, yes?

Mr Tassone: Yes. Different sponsors or manufacturers have varying levels of engagement with health professionals and pharmacists in particular. Some have been particularly engaged and proactive in sharing the information they have, and others have not taken such an interest. We are really, as a health profession workforce, yearning for more knowledge to build up our base and competency in this level because we know it's an emerging area of practice and how important it is to fulfil our obligations and duties as health professionals and in patient care.

Senator ASKEW: Mr Jackson, you mentioned earlier that, for many, the CBDs could possibly fit into the TGA regulatory framework. Earlier today we heard suggestions that perhaps the CBD could be listed as a herbal medicine or a complementary medicine. What would your thoughts on that be? I would appreciate all three gentlemen's thoughts on that.

Mr Jackson: My preference would be to see specific cannabinoids identified, their therapeutic benefit categorised and that they be recognised for that benefit. That then gives us the capacity to fit them within our normal regulatory processes. To just put it under 'a herbal product' or 'herbal use' still leaves us in a very grey area, I believe.

Mr McMaugh: I would add to that that the scheduling processes are there to look at not just the safety of medicines but also the specific reason that we use a medicine. So the burden is on those companies to say, 'This will treat this condition.' They have to back it up. I believe you'll hear from John Skerritt later today, and he'll be

able to go through those roles for you quite in-depth. But it's not just about, 'Well, it's from a plant; therefore, it's a herbal product,' otherwise we would have opiates and cocaine available that way—both are from plants.

CHAIR: That wasn't the argument they were making. Their argument was that CBD is not—

Mr Jackson: It's probably safe.

CHAIR: Yes.

Mr Tassone: I would say that, if we classified these products as a complementary or herbal medicine under our current registration scheme on the Australian Register of Therapeutic Goods and were only looking at quality and safety but not efficacy or effectiveness as we do for prescription medicines, we would be doing our patients a disservice. I think that we do have a responsibility to assess their efficacy, however possible. There is precedent for products on the Australian Register of Therapeutic Goods to be able to be registered by that pathway and to undertake the process, but it is important not only to look at the efficacy but also to gain as much of an understanding as possible for its safety in other conditions and its use with other medications. The patients who may be receiving this may have a complex history and, unfortunately, may have to take a number of medications for a number of conditions.

CHAIR: I think that's the end of our questions. If Senator Hughes has any questions, we'll put them to you on notice.

Mr Jackson: Could I just make a closing comment to reinforce something I said previously. I was previously the Chair of the Advisory Committee on Medicines Scheduling and, on an occasion when we called for public submissions on a consideration of scheduling of one particular cannabinoid, we received an immense number of submissions—many, many, many more than we have historically received on any other product. It was obvious that not only individuals who made submissions but a lot of the patient organisations that made submissions are confused about this area and sought to have scheduling changes for items that they were not clear about. So if there is one thing that could come of this, it is to have greater clarity about what we are capturing under the definition of 'medicinal cannabis', to apply our structured regulation to those items that we can capture and find another process for those that do not fit within that regular scheduling and registration process.

ACTING CHAIR (Senator Askew): I'll step in, as the chair's had to leave for a phone call. Thank you very much, gentlemen. I'm not sure that we've had any questions on notice, so we're not giving you any homework to take away.

Proceedings suspended from 15:30 to 15:49

DE SOMER, Mrs Elizabeth, Chief Executive Officer, Medicines Australia

GARDINER, Dr Vicki, Director, Policy and Research, Medicines Australia

Evidence was taken via teleconference—

CHAIR: I welcome our witnesses from Medicines Australia. Thank you for taking part in this hearing and this inquiry. I invite you to make an opening statement, and then we'll ask you a whole lot of questions.

Mrs de Somer: In the interests of time, I will try not to pause too much, because I think we've written a reasonably long statement. I understand we have emailed a copy of that statement to you for your records.

CHAIR: Just so you know, there are a number of senators in the room, with lots of questions. So, if you've emailed it, could you perhaps give us the shortened version to allow the maximum amount of time for questions.

Mrs de Somer: Absolutely. We're very happy to do that. Firstly, on behalf of Medicines Australia, thank you to the committee for inviting us to appear today. Medicines Australia leads the research based pharmaceutical industry in Australia, and our members discover, develop and manufacture the latest prescription medicines, biotherapeutics and vaccines for Australian patients, delivering over 80 per cent of the PBS by value. Our members also invest in Australian medical research and take local discoveries and developments to the world.

The crux of my opening statement is to say that Medicines Australia represents a research based industry that relies heavily on the development of sound scientific evidence to support registration and reimbursement of medicine through the Therapeutic Goods Administration and the Pharmaceutical Benefits Scheme. The Therapeutic Goods Administration has an internationally respected evaluation process that assesses the evidence submitted by medicines manufacturers to demonstrate quality in manufacture and safety and efficacy of a medicine. It will only register prescription medicines based on that evidence if it meets the high standards that it expects. We believe the community expects all medicines to meet those high standards of quality, safety and efficacy and that that should be supported by reliable scientific evidence.

The Australian government also provides the Australian population with universal subsidised access to medicines through the PBS, and medicines that are seeking listing and subsidy through the PBS also undergo a rigorous health technology assessment which looks at further evidence of comparative safety, clinical benefit and comparative cost-effectiveness or value for money against existing treatments before subsidy is recommended. We believe that the system for registration and reimbursement must be agile and fit for purpose, must keep pace with scientific and medical advances, and must minimise delays in patient access to ensure that patients have access to new medicines as quickly as possible and at least as early as in other comparable countries.

We also strongly support the role of the industry in providing appropriate education to healthcare professionals on quality use of their medicines, as they are the subject matter experts and we have a robust and universally recognised code of conduct that provides medicines manufacturers with guidance on how to appropriately interact with healthcare professionals and provide accurate, balanced and evidence based information on their products. The TGA refer to the Medicines Australia Code of Conduct regarding promotion of medicines to healthcare professionals as a condition of registration which all manufacturers must comply with and to promote a level playing field in ethical conduct.

I will leave it there. That is a summary of our key points.

CHAIR: Thank you very much. Senator Askew, do you want to kick off this time?

Senator ASKEW: I can do that. First of all, thank you very much for making yourselves available today. It's always difficult via teleconference. With regard to the framework and so on for accessing medicinal cannabis, I am interested in your thoughts on the barriers that are being faced by most GPs and so on in the industry trying to access it and support their patients.

Mrs de Somer: One of the issues that has been brought to our attention is that the majority of access to medicinal cannabis is being provided through the Special Access Scheme. The Special Access Scheme has stood the Therapeutic Goods Administration and prescribers in good stead for many years to give prescribers the ability to prescribe products that are not registered on the therapeutic goods register. But I understand that, over the last 12 months, there have been over 25,000 applications and approvals for access to medicinal cannabis through the Special Access Scheme, through the TGA. That allows a prescriber to prescribe it, but they are prescribing a product that is not approved or registered on the therapeutic goods register, so there is not a natural, direct link between a prescription and a patient getting access to the product itself.

Senator ASKEW: What suggestions would you have for an improvement to that?

Mrs de Somer: It's a very difficult area. We believe that there needs to be a strong and reliable evidence base to support the registration of all prescription medicines, and those standards of scientific evidence are well documented, well understood and well recognised. Then the manufacturers and the creators of that evidence base have to apply to the TGA for registration. The more that they can have registered medicinal cannabis products available on the therapeutic goods register the more quickly we will resolve those barriers to access.

Senator ASKEW: Thank you.

CHAIR: Senator Hughes, do you have some questions?

Senator HUGHES: Yes. Following on from Senator Askew's questions, we heard from a previous witness the difference between cannabinoids and products with THC in them and that basically products without THC should just be sold as herbal medicine. Does Medicines Australia have a view on that and on whether there is a perspective within the medicines industry that cannabinoids aren't something that should be considered as a medicinal product because of the lack of THC and should be considered more of a herbal remedy, or should they be considered in a similar class of medicine?

Mrs de Somer: I'm not a technical expert on the chemical components of medicinal cannabis. I do recognise that there is a difference and that cannabinoids and THC have different chemical properties. Obviously it is recognised that the components of cannabis that are of greatest concern in illicit use are the properties of the THC. I don't have enough information to tell me whether that naturally leads to the conclusion that cannabinoids alone are completely safe as a complementary medicine. The complementary medicines framework has a list of medicine ingredients that they consider to be safe and effective. It would be a decision of the Therapeutic Goods Administration to determine which ingredients could be accessed through a less regulated component, and I would leave it to the experts to determine whether cannabinoids fit into that criteria.

Senator HUGHES: Thank you.

Senator DI NATALE: Following on from that question on CBD, does Medicines Australia have a view about the upcoming vote on the Single Convention on Narcotic Drugs and whether Australia should express a view that it no longer be scheduled? Do you need some context for that?

Mrs de Somer: Yes, I would like some further context but I think, Senator Di Natale, that I would like to take that on notice, if that's possible. I don't have to hand whether we have formed a view on that.

Senator DI NATALE: That's fine. Why don't you take that on notice.

CHAIR: We could send you the clip from the *Hansard* so you've got the context; is that okay?

Mrs de Somer: Yes. Thank you very much.

Senator DI NATALE: Have you got a sense of how many products you anticipate will be on the register in the coming year?

Mrs de Somer: There is one product available on the therapeutic goods register right now, nabiximols. We believe that there are other products under evaluation and some that are seeking PBS subsidy. At the moment, the TGA does not publish applications for registration of medicines, so there is no transparency of how many or what medicines are going through that process. That might be a question you would like to ask Professor Skerritt when he appears after us.

Senator DI NATALE: Thank you. I will do that. Also, there is the issue of the Special Access Scheme. One of the conditions for Special Access Scheme category B is that it's an option of last resort. I think you advocate removing that. Could you speak to that.

Mrs de Somer: I'm looking to Vicki, but—

Senator DI NATALE: No, please scrap that.

Mrs de Somer: I don't think it's Medicines Australia.

Senator DI NATALE: You don't advocate for removing that at all. That's not you. That's Medicinal Cannabis Industry Australia, not Medicines Australia—no surprise!

Mrs de Somer: Around the table there were stunned looks of 'When did we decide to advocate for that?'

Senator DI NATALE: It might be a new policy.

CHAIR: It was in the memo you didn't get.

Mrs de Somer: I'm glad I didn't draft that one.

Senator DI NATALE: I'll put to you the sort of dilemma we have here. There's significant patient demand. We know that so many people are accessing medicinal cannabis illicitly. We also know that, because the evidence

base around many of these products is emerging, we don't have the level of evidence required, or indeed the companies to sponsor some of these products through the TGA. How do you think that dilemma should be resolved? What's Medicines Australia's view on how to resolve the question of huge patient demand for a product where there's certainly strong anecdotal evidence and various groups—like Epilepsy Australia, multiple sclerosis groups and others—have made it very clear that their patients have derived benefit? How do we resolve the fact that we don't have a strong enough evidence base or sponsors to put an application through the TGA, yet people are getting this drug illicitly?

Mrs de Somer: It is certainly an issue that is exercising a lot of people's minds, particularly patients and prescribers. Through the Therapeutic Goods Administration's Review of Medicines and Medical Devices Regulation a few years ago, there are some pathways of regulation where the TGA will look at early evidence and make assessments based on emerging evidence or promising evidence. Although it does still require a sponsor to make an application, there may be a place for that emerging—or limited or early or anecdotal or case study or real-world—evidence to be collated in a way that the TGA can review it.

We know that the TGA has also looked at other opportunities to expand access to medicines that don't necessarily have a value proposition for a sponsor to make an application. An example is the use of tamoxifen for prevention of breast cancer. It's a very old medicine—well genericised, very cheap—and therefore there wasn't a great commercial incentive to make an application to the TGA. But, working with sponsors, the TGA was able to identify a sponsor that was willing to put in the effort for that expanded access to be made. I think that there is opportunity and willingness between sponsors and the TGA to find a solution that still reviews evidence, is still evidence based and puts some effort in capturing ongoing evidence as it emerges—so building that evidence base over time and making a decision based on what they have in front of them.

Senator DI NATALE: Thank you.

Senator URQUHART: At this stage, I haven't seen the email that you sent. Does Medicines Australia have a formal position on the regulatory access framework for medicinal cannabis?

Mrs de Somer: No, we haven't developed a formal position. Our positions have generally been more around prescription medicines access. Given that medicinal cannabis is classified as a prescription medicine, our position is that it should follow the regulatory pathways that are available to it through the TGA and the PBS. Regarding medicinal cannabis specifically, we have limited members who are involved in this particular area of development and have not asked us to form a specific position.

Senator URQUHART: Do you have any thoughts on how we can better streamline access to medicinal cannabis products? There seems to be a really long, convoluted process. Are there any suggestions that you can make that might streamline that access for people seeking to use the products?

Mrs de Somer: I'm not sure that I have a solution. We agree that all of the regulatory processes for assessing and evaluating evidence should be streamlined and be as efficient as possible. We know from our experience that the TGA has been one of the more agile agencies in developing emerging technologies and reviewing the challenges that they present. The Special Access Scheme is reasonably efficient in the sense that the TGA has approved over 25,000 applications for special access; that is not a bad record. The difficulty appears to be in linking the ability to write a prescription with sourcing reliable, safe, effective, quality manufactured products. Maybe there can be some consideration given to how to identify the sources of reliable, safe, quality manufactured products for patients to access through a prescription.

Senator URQUHART: My understanding is that the 25,000 applications don't actually equate to 25,000 patients. Is that correct?

Mrs de Somer: Yes, that is correct, but you would have to ask Professor Skerritt about that.

Senator URQUHART: What are the challenges faced by pharmaceutical companies that wish to have medicinal cannabis products listed on the Australian Register of Therapeutic Goods?

Mrs de Somer: There is one product registered. The major requirement for an application for registration is the evidence base that is supporting that therapeutic claim. The sponsor would be required to indicate in their application what the claim is designed to treat, what the indication is for medicinal cannabis and what the evidence is that they have collected, collated, developed or created supporting that claim. As Senator Di Natale mentioned, there is a lot of emerging evidence, anecdotal evidence and, some would suggest, even real-world evidence that could be collated to support those applications. TGA experts would evaluate that evidence and make a determination on whether it supports the claim.

Senator URQUHART: And are those challenges similar or the same for pharmaceutical companies who also wish to have medicinal cannabis products considered for inclusion in the PBS?

Mrs de Somer: Yes. For the Pharmaceutical Benefits Scheme they look at not only the claims of safety and efficacy but also the comparative benefit compared to existing treatments.

Senator URQUHART: Is the framework for conducting clinical trials appropriate for medicinal cannabis?

Mrs de Somer: Clinical trials are an area that Australia has a real opportunity to improve in. The regulatory framework for initiating clinical trials can be lengthy and onerous due to regulatory differences between states and territories, and we have heard that there have been hold-ups to getting clinical trial materials through the border. It would be disappointing if clinical trials that were set up to examine medicinal cannabis were held up in accessing those products by barriers created by our borders. Accessible clinical trial products should be as streamlined, efficient and regulation free as possible.

Senator URQUHART: So how can we encourage more clinical trials of medicinal cannabis products?

Mrs de Somer: Streamlining the requirements for developing clinical trials; ensuring that there are limited or no barriers to products gaining access to the country; and giving guidance on what kind of evidence the TGA would like to see to assist those companies in designing clinical trials that will benefit the patients that will have access, but also develop the evidence that is required to support their claims.

Senator URQUHART: Great. Thank you.

CHAIR: As there are no further questions, thank you very much for your evidence today. It's very much appreciated. The secretariat will send the *Hansard* that Senator Di Natale was referring to for that question on notice.

Mrs de Somer: Lovely. Thanks very much.

Dr Gardiner: Thank you.

BAXTER, Dr Leslie (Les), Director, Agricultural Research and Development, Tasmanian Alkaloids

CROCK, Mr Peter, Chairman, Medicinal Cannabis Industry Australia

FAENZA, Ms Elisabetta, Director and Board Member, Medicinal Cannabis Industry Australia

MURDOCH, Dr Ross, Chief Executive Officer, Tasmanian Alkaloids

XINOS, Dr Christina, Medical Director, Australia and New Zealand, Canopy Growth Australia

[16:12]

CHAIR: Welcome. I know some of you have been here for a while. You'll be aware that we've had a large number of witnesses and that we've been quite vigorous in the number of questions et cetera. I now invite each of your organisations to make an opening statement. If you could keep them relatively brief so that we can maximise the use of your time for questions, which we will all have, that would be appreciated.

Dr Xinos: Spectrum Therapeutics is a subsidiary of Canopy Growth Corporation, which is the largest legal cannabis company in the world. We are listed on both the New York Stock Exchange and the Toronto Stock Exchange, and Spectrum Therapeutics is the medical arm of Canopy Growth. In Australia we only operate under Spectrum Therapeutics.

Spectrum Therapeutics has supplied high-quality medical cannabis products to hundreds of thousands of patients across the world. We're also excited to be building a new facility here in Victoria. We thank the federal government for awarding major project status to our Australian project. Once fully operational, we will be employing over 200 people at our facility in Victoria. As the medical director of Spectrum Therapeutics, I have a medical science liaison team that interacts directly with doctors and pharmacists to help address gaps in their knowledge and provide education, and it's in that capacity that I am bringing their insights to you today.

Firstly, I'd like to compliment the government on what is going really well. Spectrum Therapeutics recognises that the federal government has taken a number of important steps to support medicinal cannabis in Australia. This includes: allowing the importation of medical cannabis through the TGA; establishing a streamlined portal for the Special Access Scheme B applications; imposing strict standards and testing requirements on medicinal cannabis products through federal law, which is TGO 93, which ensures that what is on the label is actually in the bottle; and pledging \$3 million from the Medical Research Future Fund to research the benefits of medicinal cannabis for cancer patients.

I've talked to you about the things I think the government's doing really well. I also think that there are opportunities to be a bit more innovative and to address some of the issues. Some of the issues that we think could be improved are around prescribing, education and affordability. With prescribing, one of Spectrum Therapeutic's main concerns is that it differs from global best practices. The Special Access Scheme talks about the 'last line of therapy' option. If you look at organisations in a number of other countries—for example, the European Pain Federation and the Canadian Pain Society—their consensus statements have listed cannabis as a third-line option so that patients don't have to exhaust four or five different therapies before they can access this therapeutic option. So we can learn a lot from other countries.

Also, the Special Access Scheme B has been designed for special circumstances where patients have exhausted all other options, and it's been very productive in that over 3,000 patients have been approved month on month most recently, and 70 per cent of those patients are chronic pain patients. So now we actually have a lot of evidence of chronic pain patients getting very fast approvals from the TGA. We think an innovation here could be looking at moving medicinal cannabis for certain indications from category B to category C. The category C Special Access Scheme is a notification system, so you don't actually have to provide clinical justification and go through the lengthy process; you just have to notify. This also is a great source of real-world data for the TGA. We're talking about gaps in evidence, so there is an opportunity here to be a bit innovative and actually have a notification system and collect data that can be used to create a white paper submission to the TGA to get approval for certain medicines for certain indications. So those are our suggestions for solutions around prescribing.

The next point I want to make is on education, because I have a medical science liaison team speaking to doctors and pharmacists every day. What has been highlighted is that there's a real gap in knowledge. Some doctors don't even know that medicinal cannabis is legal. So we find that that's a real barrier, and conversations are starting at a very early stage. We think that there is a role for medical universities or pharmacy colleges to be teaching it. From our perspective, we are running company-sponsored education. Our education is RACGP accredited, but we feel it's not just the role of the sponsor; it's much broader than that.

Another factor here with education is that we have a medical science liaison team because there are barriers to how much information we can share with doctors. We cannot promote our products. We cannot list our products on our website. It's been highlighted today that a lot of doctors don't even know what products are available. They don't know a product is out of stock until a patient goes to the pharmacy and tries to fill a script. Ideally, it would be great if there were a TGA website or some capacity where doctors can look up the product they want to prescribe to see if it is currently in stock so that they don't have to go through the whole process of putting through an application only to then find out the product is out of stock and they have to redo the application. And just to highlight other areas that we can improve on in education, we're hearing a lot from doctors that they want peer-to-peer mentorship. They don't want to learn from us; they want to learn from their peers who have prescribed medicinal cannabis who have had success, so that they can have that confidential discussion. So peer-to-peer mentorship would be a great avenue that the colleges could also facilitate. And we can also learn from other countries. The New Zealand Ministry of Health has budgeted to facilitate education for GPs, and we think that Australia should follow suit.

The last point I'd like to make is around affordability. Medicinal cannabis remains prohibitively expensive for a lot of patients because the products aren't registered and aren't available on the PBS yet. And because of affordability, we're seeing a lot of patients turn to the black market. If there were some innovative mechanisms so we could work with the TGA to have our products registered, we definitely would be open to those discussions.

On white paper submissions where the TGA and companies can evaluate the existing data, not having large randomised control trials doesn't mean there's no data. There are over 10,000 clinical papers with data on medicinal cannabis. There are precedents: the TGA has done white paper submissions in the past for other products. We think that medicinal cannabis could fit nicely in that bucket. With a quicker, easier and more streamlined process for us to get our products registered, we could apply for pricing through the PBAC. Then it would become more affordable, and it would be a very similar mechanism to what patients are currently used to.

CHAIR: Thank you.

Mr Crock: I am the chairman of the MCIA, and I'll make an introduction on behalf of the industry association. We formed a couple of years ago on the basis that we knew that the regulator would need an industry voice to provide feedback, as opposed to individual companies. The six founding members were the first six licensees under the new system.

The MCIA is supportive of a regulatory framework that enables the development of a medicinal cannabis industry in Australia and access for patients, but what we do require is to see this process streamlined. The MCIA is working to enable access for patients to quality controlled, true-to-label, compliant product. While the number of patients seeking access has grown rapidly, it is significantly less than the number of patients who'd be looking to legitimately access medicinal cannabis if approval processes were improved. Improving and streamlining the existing legislation and operations of the ODC is the best option to facilitate patient access to timely, cost-effective and quality Australian product. Its shared objective is for Australian product to reach Australian patients at an affordable cost. The first priority must be, therefore, to address regulatory barriers. I won't go into all of these now; we've made a submission, and it's probably best that we refer to questions so you can come back and ask us.

The second priority that we see is to promote confidence across patients, doctors, government and the community. This is best delivered by operating under the existing regulatory system.

The third priority is around affordability, which is an issue for many patients. The key point under this is the need for a compassionate pricing system. We know that, at the moment, an unregistered product is not applicable under the PBS, and we need to address that.

There are a range of other issues that impact patients, including driving and/or working while taking medicinal cannabis. That's an area that needs to be addressed.

We believe the way forward to improving patient access is to ensure the highest quality standards are maintained, ensure products are affordable and available as needed, raise the industry's profile as a trustworthy and reliable industry, and remove unnecessary regulatory processes and allow medicinal cannabis companies to work. Thank you.

CHAIR: Thank you.

Dr Murdoch: Good afternoon. Thank you for this opportunity to present. I'm the CEO of Tasmanian Alkaloids. Tasmanian Alkaloids is an Australian based company. It is one of the world's premier biological and botanical extract companies, specialising in the cultivation, extraction and supply of controlled and regulated products. We support the healthcare and pharmaceutical industries. We've had over 40 years of experience in

understanding and operating within both local and international regulatory requirements, including those associated with the movement of controlled substances. We've got a strong history also of reinvesting profits into chemical R&D and innovation in this area. We think this is important as something that should be driven in the cannabis area as well.

To put our operation into perspective, we're located on a 50-acre site in Tasmania, just outside Launceston, and at present we are in contractual arrangements with 250 to 500 farmers. This is an important aspect when we think about the industry itself. We are TGA and FDA accredited and operate under GMP already. We are presently investing in an additional multimillion-dollar cannabis extraction facility on our site, and this will be the third facility that's capable of cannabis extraction. Our largest extractor has the capacity to handle in excess of 30 tonnes of biomass a day, which gives us the potential to produce tonnes of CBD per day for the Australian industry.

We believe that cannabis has the potential to provide a great benefit for Australian patients, the Australian agricultural and healthcare industries and the broader Australian economy. But we also believe that it will require appropriate and reasonable regulation if we're to ensure that Australian patients have adequate, safe and affordable access to medicinal cannabis and other cannabinoids. We believe that, to succeed, the regulations should first and foremost ensure the quality and safety of product that's delivered to Australian patients. We need regulation that creates at least a level playing field for Australian companies and recognises the difference between the cannabinoids so that non-THC cannabinoids, such as CBD, can be more affordably produced at broadacre scale. We believe that we need to allow dual use of crops such as industrial hemp to allow the harvest of seeds and fibre and the extraction of CBD and other cannabinoids. We need regulation that protects Australian companies in a way that allows us to promote their ability to invest back into research and innovation. We think the regulations should align with IACB and international regulations to allow companies in Australia to compete on a level playing field in relation to exports. Ultimately, the regulations that are brought in need to reduce the burden on regulators, doctors and the industry around non-THC cannabinoids. Thank you.

CHAIR: Thank you very much. Who wants to kick off?

Senator BILYK: Dr Xinos, this is a bit of a clarification, really: you mentioned stock levels and things being out of stock and then people having to go through the process again. I'm still confused as to why the process has to be gone through again.

Dr Xinos: From a TGA perspective, when you apply for a Special Access Scheme B patient, there's a drop-down menu for the product, so you're applying for approval to have that product for that patient. If that product is not at the pharmacy or is out of stock, you need to go through the approval process again. Doctors can clone the application form so that most of the information goes to the new application, but they still have to fill in some bits and pieces and it still has to go to the TGA.

Senator BILYK: So are you saying that, if something's out of stock, it's no longer available at all?

Dr Xinos: Yes.

Senator BILYK: So they have to go for a different product?

Dr Xinos: Yes. If products are out of stock, say, for several weeks, that patient is left without medication, so they try to source a similar type of medication from a different company, for example.

Senator BILYK: Yes, a few weeks can be quite critical to people wanting to use it.

Mr Crook: The key issue there—this is the industry association point—is that nearly every patient in Australia that's been prescribed cannabis to date under the Special Access Scheme has used imported product. No product produced here in Australia has yet made its way in volume to Australian patients. Those who had imported product were limited to a 12-month shelf life—so they had limited imports that they brought in. The requirement for the industry association to see streamlined access for Australian grown and produced product is really the key issue that we believe needs to be addressed.

Senator BILYK: So where's the hold-up for the Australian-made products?

Mr Crook: The process as it stands at the moment is that you go through the licence process first, and then beyond that is a permit process. We believe that the focus of the ODC, in the way that it was set up, is to do two things: to provide access for patients to therapeutic products and to remain compliant with the international regulations. They have got to meet International Narcotics Control Board requirements. There has been too much focus on the licence application process; that's taken too long. The ODC have been under-resourced. They have now processed over 200 licences. For those who are through the process and looking to operate under a permit,

we've had delays in getting timely responses to permits which are the key to the production of product to take through the system.

Senator DI NATALE: What's the delay about—sorry to interrupt.

Senator BILYK: That's all right. Following on from Senator Di Natale's question, a number of submissions have suggested that the ODC is under-resourced. Would anyone at the table like to make a comment on that?

Ms Faenza: One of the difficulties with suggesting that we need another body is that you would be starting from scratch and would have all the same teething issues that the ODC has gone through. Just as we are in a sense a start-up sector, the Office of Drug Control itself, in regard to approval of licensing and permits for the conduct of an industry, is also a start-up. It was a prohibition body previously. It has been understaffed and under-resourced for the entire period of this process. The Deloitte feasibility study that was done said that there would be something like six licensees applying, not hundreds. The staffing and funding model that was developed reflected that tiny number of expected licensees, whereas what we have is hundreds of applications.

The other limitation as I understand it—and I'm sure the ODC, when they speak, can correct me if I'm wrong—is that they have to assess these applications in the order that they are received, not on merit. Initially there were many applications that were frivolous, not well thought through and had no chance of commercial success or operation. But they had to process all of those applications and read every single word of them in the order that they were received, not in order of actual commercial viability or strength of application.

What then happens is: if you have a small number of people who are working very long hours and are under a lot of pressure to get these applications through, who have you got left to deal with audits, site visits and permits? In our case, my organisation of LeafCann Group, we have three licences: one for research, one for production and one for manufacturing. Once we got those licences approved, we began the work of site preparation and construction. If our licences had not been approved, there would have been no point having a building built. If we had needed to make amendments to what those licences needed to be to get approval, we wouldn't have wanted that building already built. So you have this one- to two-year lag in the processing of a licence. Then you have at least 12 months in the building of very high-tech facilities, the raising of many millions of dollars and the funding of your staff through that whole process as you are building your expertise base.

After that, you go for your audits and permits. But it's not just the permit to operate and actually commence production; you have to go through quarantine to bring in your genetic material, and ensure that the outgoing country and the quarantine service here are in agreement on the type of genetic material coming in to start off your process. Many companies have seen that material die in quarantine. Can you imagine, when you've spent years getting to that point, your material being killed in quarantine? That's a hold-up.

After you get that in, you might have issues, where you have multiple licences within a company, getting approval to move the genetics from one licence to production—which is still your company but under another licence—to your manufacturing, which is under a third licence. Some companies I'm aware of have waited inordinate amounts of time to have this material moved. I would say it's not because of a lack of will from the Office of Drug Control. It's two things. One is massive understaffing and underfunding, and the funding model just does not work. The other is that there are sometimes no legislative mechanisms to make that movement possible. How can you get an approval if there isn't actually a piece of legislation that allows the movement of that schedule material from one place to another?

The other part is that we also sit under this international regime, and there are limitations on what Australia can do while being compliant with the single convention and in reporting to the INCB. We often hear about CBD that it should be produced, say, broadacre, but under the single convention the flowering tops are specifically prohibited from the production of cannabinoids. It is only the seeds and the stalks that are allowed to be extracted for cannabinoids under a hemp licence, as opposed to a medicinal cannabis licence.

Sitting here today—and listening, through your app, throughout the day as I was coming to this hearing—what I've heard is lots of people conflating legislation, lots of people conflating what cannabinoids are, what a well-formulated product is, and what they can and can't do under the law. We are limited by legislation internationally, nationally and at a state level, and as producers we have to comply with that. We cannot break the law. We cannot even consider breaking the law or we would lose our licences and, in some cases, probably face criminal charges.

We want to get affordable product to patients. That is why we started. I was born with a rare disease. My parents sold everything they had to keep me alive. I don't want other parents to have to sell everything they have or break the law to get product for their children or family members. It is ridiculous that, in this age, we are going through this process. You cannot, with one hand, legalise medicinal cannabis and then, with the other, not fund it so it can work. We need to change the funding model so that it can work, so that we can have enough staff, so that

an Australian sector can move ahead. We're all in a holding position right now. We want to make product. We want to get it to patients. International companies want to import product, engage with the Australian market, produce consistent product and sell that at an affordable price.

None of us are here because we're greedy. We're here because we are passionate. I can tell you four years spent doing this isn't because you're greedy; it's because you're dogged and determined to get a result for the Australian public. But the ODC need help, and I am really hoping that you, Madam Chair, and your esteemed committee here, will find a way that actually works, that doesn't ignore international law, that isn't based on fairyland ideas of what is possible but funds what we have so it can work efficiently.

Senator URQUHART: Thanks.

Senator BILYK: Can I just ask Tas Alkaloids a question?

CHAIR: Yes, since you're from Tasmania!

Senator BILYK: I knew one day it would pay off! Dr Murdoch, you mentioned in the submission that the regulations for the production of CBD preparations are too stringent. Could you explain why you think that and how you think the regs could be changed to help.

Dr Murdoch: Certainly, our intent, or our dream, is to have CBD available to be grown broadacre. We believe that Australia can produce product for itself. We think that some of the difficulty that the industry is having at the moment is that the restrictions around how you can grow crop that is to be extracted adds to its price. In fact, we find ourselves buying raw material that costs more than the finished and extracted material that can be brought in internationally.

A lot of that is around the conditions under which it can be grown. We're very familiar with the narcotic industry—poppies grown in Tasmania. Those products have strict regulations that ensure the quality and that regulate who can produce, what can be produced and how much can be produced, and yet the conditions under which you can grow them are considerably less onerous than those for cannabis. Certainly also if you look to extract from a product like industrial hemp, rather than get it for seed or fibre, there are completely different conditions under which you can grow the same crop. So we see that there is an opportunity. The crops are being grown—industrial hemp is already being grown. The capacity is available.

I do agree with some of the discussion around the duration it has taken to get all of those agreements, but I think we have a viable industry here, or we have capacity to build a viable industry. The concern is with getting raw material that is of a quality and cost and amount, and then for us to move forward from there.

Senator BILYK: So you don't think it's a level playing field, do you?

Dr Murdoch: No.

Senator BILYK: Can you talk to us about what you mean by that and say what the issues are?

Dr Murdoch: If you look at the North American industry at the moment, in fact they suffer from a glut of product. We've seen a roller-coaster for companies there. A lot of them built their infrastructure and built their market cap on their ability to have a high-cost product. The cost of that product has come down considerably as people have invested in relatively large production. They do not face the same restrictions, the same cost and the same set-up delays that we do, and each of those: the cost—

CHAIR: The regulatory process—

Dr Murdoch: and the regulatory process as well. So all of those things cost. For a company that needs to get in cash, carry that cash and carry that projection forward over that period of time, with all of the risk, that all subtracts from the ability to produce very affordable product, and I think it is at the moment not a level playing field for us to compete with the imported product.

Mr Crock: I think it's worth noting that the glut in North America is actually focused around the recreational market that everyone has chased after there and that in fact GMP pharmaceutical-grade medicinal cannabis is in short supply, in Europe in particular but in all parts of the world. Access to a well characterised and understood product—which is largely what patients are looking for—

CHAIR: Sorry—can I ask: is that in response to the new laws in a number of states in the US and also in Canada? Is that what you are saying?

Mr Crock: Correct.

CHAIR: So companies have shifted into recreational supply?

Mr Crock: There was a green rush into what they saw was a 10 times larger market, and they all raced in. The whole North American market at the end of last year, particularly for Canadian companies, got turned on its head.

But it was all driven by, in fact, Canadian legislation not keeping up with the recreational market, where not enough stores were open and other things, so it didn't pan out as people expected it to. But the medicinal cannabis market has continued to grow in Canada and product is still in short supply there, and particularly in Europe—Germany is an example—where they can't get access to GMP grade product, which is what we are setting up an industry here for: to play in that space. That's where we believe there's a role for Australia to play.

An interesting point is that New Zealanders have watched what's happened here and I think they're looking to leapfrog Australia, particularly in the research area where they've realised that we've set up too restrictive an environment to allow for research and development in this space. That's another thing that I think we need to look at, in terms of changing the legislation and the reliance on that legislation—or it's too prescriptive, and we're being forced to take too narrow a view on how to work with medicinal cannabis in Australia.

CHAIR: Senator Di Natale?

Senator DI NATALE: You've sort of answered a number of my questions, because I was going to ask you, 'Why are we running out of stock if there's a glut?' But what you're saying is that there's a shortage of medicinal cannabis, and we're a small market, I imagine, so other markets take priority?

Mr Crock: Correct. And it's difficult to bring in. But the bigger issue is that no Australian product has yet made its way into the market.

Senator DI NATALE: That is obviously a concern. But I've heard many of the reasons for that delay. I want to ask what the prospects are of having some Australian product come onto the market soon. What time line are we looking at? Maybe that's not something you can answer, because there are still—

Mr Crock: No, we've got product coming through the process now, and we're taking it through with the TGA, and that's where we believe there is a role for both the TGA and the ODC to play. It needs to be streamlined between the two, but we have products that have been formulated and put on the stability now to meet all of those requirements.

Senator DI NATALE: So are we expecting Australian product to be able to fulfil the demand that we're seeing? Your comment, Dr Murdoch, was that we should be able to supply Australia. When do we think that's going to happen? Is that a decade away?

Mr Crock: No, it's less than a decade away, but investing—Cann Group, for example, had the first licence in Australia and have been cultivating since May 2017 for the Victorian government, through that system, for patients under their paediatric epilepsy trials. But we're now stepping into and formulating product that will go for other clinical trials and be available for patient prescription.

Senator DI NATALE: Following on from there, what are you expecting in terms of Australian product, and—this will be a question for the TGA—how many applications are with the TGA at the moment?

Mr Crock: The Special Access Scheme is actually working well in terms of treating medicinal cannabis as an unregistered product. For us to allow access to it—I agree with Christina's point that it shouldn't be a last-resort access.

Senator DI NATALE: So you could support the category C call?

Mr Crock: Absolutely. It shouldn't be seen as a last resort. So that will accelerate access for patients. The issue that is going to come up very quickly is affordability for patients. Taking it through a TGA GMP process is not cheap, but it can still be affordable. But we need to look at the Pharmaceutical Benefits Scheme, which currently won't allow an unregistered product to be covered under that.

Senator DI NATALE: Why is it so expensive at the moment? To be very straightforward, is it the regulatory hurdles in terms of bringing the product in or is it implicit in the manufacturing overseas? I don't understand why a product that can be grown so easily—and in most cases it's a pretty straightforward extraction process—translates to \$50,000 a year in terms of treatment.

Mr Crock: There's no doubt there's been some opportunistic pricing in the market, and there's no doubt that the black market is thriving under this current environment. They're the biggest winner out of everything.

Senator DI NATALE: Yes.

Mr Crock: But it's also wrong to assume that you can grow it at home and have a quality product that meets TGA requirements. In terms of having a product that's well characterised and that doctors can trust, if we took it through a normal pharmaceutical development pathway we'd be talking \$40 million to \$300 million over 10 years for a single product, to get it to market—

Senator DI NATALE: Sure, but we're not doing that at the moment.

Mr Crock: We're not doing that.

Senator DI NATALE: And we're sourcing product from overseas. I don't get why it's so expensive. I don't understand what the costs are.

Ms Faenza: The production is not actually the biggest cost. I've done comparisons between broadacre, greenhouse and enclosed grow—completely controlled grow. We're talking about the difference of a dollar a gram, so that is not the source of the cost. We often hear the argument made that it's the indoor grows that are making it expensive. Actually, it's not; that's not really contributing to the end price. It is all of the middle processes—the regulatory processes, the testing and the many hands in distribution it has to go through. It's all those middle hands that have ramped up the price, especially when it's imported, because there weren't many warehouses that were set up to receive these imported goods. They were charging very big fees for the import and warehousing of those products from Canadian companies. And then there's the distribution. Because it was novel, it was new, people weren't set up at scale. So we've seen all of that, and then the actual distribution to the patient adds more cost.

Senator DI NATALE: So, when there's more Australian product online and we start producing at scale, you'd expect the cost to come down quite dramatically, I'd imagine.

Ms Faenza: Yes.

Mr Crock: Costs will come down and patient access will be improved. In terms of things like having a repeat prescription and being able to go back to get the same product, available and on hand, that's where patients will benefit from that as well.

Ms Faenza: And I also think that, with Australian companies all looking to develop products for a number of different niches, what you'll have is the pharmacopoeia effect of medicinal cannabis. Rather than, 'Is it high THC or high CBD?' and then whatever that is—you use it for 10 different things—there will be well-characterised products that will have a whole profile of minor cannabinoids and terpenes in them, or they'll be isolates at a particular concentration, and you'll know that that's the one for that condition. Right now it's quite hit-and-miss, and that's because it's been banned for so long and it's early days. We're caught; we want to be here, but we actually have to do what penicillin did a hundred years ago and become an actual medicine. We're not there yet.

Senator DI NATALE: Dr Xinos, you're involved with a global company. If you're a GP in Canada, what do you do to write a script? Is it as simple as you write a script and someone goes to the dispensary and gets it?

Dr Xinos: Correct. Right now, if you're a patient in Canada, there are two ways you can go to a dispensary and get medicine. But what we're seeing, as Peter said, is that patients still want to see doctors. Patients are going to doctors. Doctors are writing a medical authorisation for the patient and may limit how much THC they have per month. So it's an authorisation, and they put a limit on what they allow, and then that patient contacts the licensed producers. They can pick whoever they want to buy their product from and can order it from online through their websites, and it gets posted to their home.

Senator DI NATALE: So what's different about Canada and Australia? Why have we decided that we have to create a convoluted process for a GP to require a specific approval for a specific product? They run out. They have to do it again. That puts off a lot of GPs. Why is it that a GP in Canada—I mean we're not talking about a developing country; we're talking about a comparable country—can make a decision to write a script or an authorisation for a patient, and they can go off and get the drug that they need?

Dr Xinos: I think that Canada's got a lot of experience. They've had medicinal cannabis available to them for almost 18 years. The Cannabis Act really changed—the legislation allowed for that. In Australia we don't have that much experience and we don't have that law, and our patients are used to going to a chemist to pick up their medicine. That's not a bad thing, actually having that counselling with the pharmacist, who talks them through drug interactions and explains how to take the medication. Even with all of the information that we provide to patients about dosage and administration, they still spend a considerable amount of time with the pharmacist taking them through that. I think they're a much more mature market, and they do have some laws that allow it. For Australia, I don't think we have anything else like that, so it would be very novel for us.

Ms Faenza: Pharmacists opted out in Canada. They opted out. They did not want to touch it.

Senator DI NATALE: They didn't want to be involved.

Ms Faenza: Yes.

Mr Crock: But I think the issue is that most or all Australian doctors that I know don't regard that as a true medical system, where the patient goes and chooses what product they want to take after they've got an authority.

I think we've set up the right framework. The issue is that we haven't got access to product for patients here, and that's why it becomes convoluted and there are delays.

Senator DI NATALE: You say we have the right framework. As I said, from the perspective of GPs who want to be involved in this—and there are lots of them; we heard earlier today that a lot of GPs want to be involved—it's just a nightmare, a bureaucratic nightmare.

Mr Crock: It's a bureaucratic nightmare, but there are also a lot of them who aren't aware of what's there. So education is the other part of that.

Senator DI NATALE: Yes. Education is one part, absolutely—and I'd be surprised if anyone on this panel disagrees with the importance of more rigorous education for GPs who want to inform themselves—but then there's also that GPs are time-poor. They don't want to have to spend five minutes, even three minutes, going through a process that's not required of them if they write a script for a much more dangerous drug like an opiate.

Mr Crock: I think that's the key. The Special Access Scheme has been improved in terms of efficiency, but it's potentially an unnecessary burden on the doctor who doesn't have time. That's another part of the consultation cost for someone looking to get access to medicinal cannabis. It's higher because the doctor has to take up to 45 minutes to go through that whole process, and that scares a lot of them away as well. So I think you're right: that's an area that could be improved.

Dr Xinios: To that point, we've had feedback from doctors who recognise that to do an application properly takes time. It takes at least 20 minutes, if not longer—

Senator DI NATALE: Per patient?

Dr Xinios: Per patient, especially if it's the first one. When it's a repeat it's easier because you can use the clinical justification you used last time. But the first time you do it takes about 20 minutes, maybe longer, because you have to put a clinical justification and your monitoring steps and get the patient to sign informed consent, so there's a lot you have to go through. I think something that could facilitate access would be to have an MBS item so the doctors could get reimbursed for the time that they spend with the patient to fill out an application. That's the feedback that we've gotten from doctors.

Ms Faenza: I think the risk you've got in Australia, which is very similar to what's happening in the UK, is that it's much simpler if you go through a specific clinic that is set up specifically for cannabis, and that's all about: can you afford to pay for it? So you end up with a two-tier system in Australia, which is what's happening in the UK, where if you've got the money you can get this really fast and legally. If you haven't, it can be a nightmare. I think it would be very un-Australian to have a two-tiered system where, if you have the money, beauty, you can get whatever you like and you can get it legally, and if you haven't you are stuck in a system or you get it illegally.

CHAIR: We have to move on. Senator Askew, do you have some questions?

Senator ASKEW: I do. We've heard a few times today the 'medicine of last resort' quote. I want to clarify exactly where that's coming from, because my understanding is that it's not the first line of medicine, but, after that, it's up to the prescribing doctors as to whether they want to go through the process, through the Special Access—

Dr Xinios: In the Special Access Scheme, to use an unregistered product the guidelines suggest that you have to have tried every registered medication first and that, when you have exhausted all other registered medications, regardless of safety, you can apply for unregistered medicine. And, when a patient is applying for the unregistered medicine, the doctor has to list, in the clinical justification, every single medicine that the patient has tried, explain why they think medicinal cannabis is going to work and attach clinical papers or other justification as to why they feel it's appropriate. It's part of the TGA guidelines.

Senator ASKEW: We heard evidence this morning from an individual who had similar experience. I'm trying to clarify exactly where it is. So it's the TGA guidelines. We might need to look at that later on. Dr Murdoch, you mentioned a couple of things earlier regarding reinvesting in chemical R&D. Obviously that's something that we would hope any producers are doing in the country. Is there any clinical trial underway with Australian products that we are investing in at the moment?

Ms Faenza: We've begun the preclinical work for dementia.

Dr Murdoch: We're an extraction company. We have certainly been doing some agricultural R&D. Les is here at the moment. The aim has been to improve the yield, and improve the quality, the reproducibility and the ability of the plants to be appropriate for the climate. So it's about increasing yields and ultimately decreasing the cost associated with growing and extracting.

Senator ASKEW: So, in the longer term, that will hopefully reduce the cost, once it's all finally—

Dr Murdoch: Correct.

Mr Crook: The Victorian government started with the paediatric epilepsy cohort. We were producing product for that—raw material for them to use.

Senator ASKEW: So the trials are happening?

Mr Crook: They've stepped away and they're making that product available for a wider range. Clinicians can apply for access to that product. We've also got work with the Olivia Newton-John Cancer Research Institute in looking at quality of life, pain and late-stage cancer care.

Dr Xinos: Canopy are also doing a number of trials in Australia. We're doing the phase 1 clinical trials on our products, but we're also working with a number of different groups in different therapeutic areas, especially oncology and endometriosis, to do research in those areas.

Senator ASKEW: It's good to know that things are actually advancing in that area. The other question I have is on dual-purpose crops. I want to have a better understanding of what the barriers are, because obviously we can't do it. What needs to be removed to allow it to happen from a legislative perspective?

Mr Crook: From our experience, once product has been cultivated under a medicinal cannabis permit, it must be for medical use only. Any by-products are deemed prescribed waste and have to go to medical waste. So it's a high-cost pathway. If that could be used for fibre and other areas—if that's what you were talking about—

Senator ASKEW: Is that something in your agricultural—

Dr Baxter: Currently, you have to nominate whether you're growing a crop for industrial hemp or medicinal cannabis. If you grow for industrial hemp, it's under state jurisdiction and you can't extract from it. If you want to grow it for extraction, it comes under medicinal cannabis legislation and that controls the way that it's grown. It has to be grown under the Commonwealth legislation and that limits what can be done. We have growers who are growing industrial hemp, and there will probably be about 5,000 hectares grown this year and maybe 10,000 next year.

Senator DI NATALE: In Tassie or nationally?

Dr Baxter: Five thousand in Tasmania, so nationally there would be a little more than that. Next year there will be around 10,000 nationally. If you assume that there's maybe two per cent CBD in the residual plant, you're talking about up to 200 tonnes of CBD that is potentially there and currently not accessible to the pharmaceutical industry for extraction.

Senator ASKEW: Okay. So that would definitely require a lot of legislative change to fix. We can look at that.

CHAIR: I can't think of it at the moment, but there may be a really good reason why that happens, so we also need to chase down why.

Senator ASKEW: Does it happen internationally? That's the other question.

Ms Faenza: Under international law under the single convention, you cannot use a hemp crop for the extraction of cannabinoids. That's overarching. Some countries handle it differently internally, but we've seen the movement of CBD product internationally breaking those conventions. It has been made from flowering tops in, say, America or China and has been shipped to the EU or Japan, where that international movement of goods would actually prohibit the movement of product extracted from flowering tops. We've had countries—

CHAIR: Tops and bells then?

Ms Faenza: That means the flowers as opposed to extracted from the seed or the stem, which would be legal. But it occurs in such low percentages because the cannabinoids are metabolised by the time you get to the seed. And so what's happened is that some of those jurisdictions have done a track and trace, discovered that this is not compliant and refused the product, and in some cases they have sued the companies that passed off that this was internationally compliant. The UK right now has a massive problem with a flood of so-called CBD products, most of which don't contain CBD and often contain THC and other contaminants, and who knows where they come from. They're trying to clean that up at the moment, and that's a really big mess.

CHAIR: Can I jump in there? We're going to have to move on, but I want to be clear that, from what I can gather from what you've just said, it's actually the international regulations that are prescribing the way that we in Australia are treating the two crops; hence the fence around medicine et cetera.

Dr Baxter: Opinions vary. We would maintain that there actually are quite significant quantities of CBD in the residual minus the flowering parts, which we would extract for the grain. Therefore, we would maintain that,

whilst it's true that the international regulations do have some bearing and would make it a lot easier, they're not necessarily the only restriction at this point in time. There is some inconsistency or tension between state and federal jurisdictions. That could be sorted out and would make life easier.

CHAIR: So you wouldn't solve it just by dealing internationally; there are also Australian things.

Dr Baxter: There's potential to do that, yes.

Mr Crock: We as an industry association think there's more to be gained by streamlining and getting the existing legislation working properly and by broadening it to that at this stage.

Senator DI NATALE: Do you think it's a big potential exporter as well?

Mr Crock: It is, particularly because the TGA stamp of approval that we bring here in Australia is sought after. There's no doubt that that carries great weight, and we believe it's going to underpin excellent export opportunities for Australia. That is also important in streamlining and getting access for Australian patients. Operating at scale is a key part of that. So it's not that we're chasing an export market ahead of Australian patients, but Australian patients will benefit from an industry that is set up and working properly under a TGA/ODC structure.

CHAIR: I've got one last question. I want to go back to this issue about the education of GPs and doctors. Is the argument for Canada that, because they've had medicinal cannabis there for 18 years, over that period of time they've been through what we're going through? Is that a fair assumption?

Mr Crock: There were a number of high court challenges in Canada that related back to their constitution. Health care was enshrined within that. That's where the high court stepped in and said, 'No, the government cannot stop a patient getting access to product.' That opened the home-grown solution for patients, so it's a different framework altogether.

CHAIR: I'm focused on the education of doctors bit, because that's come out very strongly today and we spoke about it a bit earlier. From what I gathered from what you said earlier, doctors in Canada are now very well educated on issues around use of medicinal cannabis. They're not going through the same problems that we are. Is that true or not?

Dr Xinos: I think there is still the whole spectrum of doctors. There are some who still don't want to prescribe. Some think it might be okay for you to go to the dispensary and work it out. Some will actually manage their patients. I think we will see the same with Australian doctors: some will be very open to it and will want to learn and prescribe for the right patient. There are some who won't.

CHAIR: So the Canadian markets do have the same issue but have had more experience over the years.

Ms Faenza: And they've left a lot more to the patient making decisions and educating themselves, so it's been very patient driven. A lot of doctors, as Christina said, will just say, 'Here's an authority.' Off the patient goes. They pick the product as long as it's under the total THC limit the doctor has suggested. And so the patient has educated themselves as to what they think they need, and they're speaking to people who are dispensing the product and may know about growing it or maybe recreation. But, having had team members travel the world and feed back to us, I'm not convinced that that's necessarily a great medicinal model.

CHAIR: Okay. Thank you very much for your time today. It's very much appreciated.

MASRI, Mr George, Assistant Secretary, Regulatory Services and Drug Control Branch, Department of Health

PEGG, Dr Grant, Assistant Secretary, Pharmacovigilance and Special Access Branch, Department of Health

SKERRITT, Adjunct Professor John, Deputy Secretary, Department of Health

[17:05]

CHAIR: Welcome. Thank you very much for coming today and for being here throughout the proceedings. I remind witnesses that the Senate has resolved that an officer of a department of the Commonwealth or of a state shall not be asked to give opinions on matters of policy and shall be given a reasonable opportunity to refer questions asked of the officer to superior officers or to a minister. This resolution prohibits only questions asking for opinions on matters of policy and does not preclude questions asking for explanations of policies or factual questions about when and how policies were adopted.

I invite you to make an opening statement if you wish to, and then we'll ask you a lot of questions.

Dr Skerritt: Very briefly: people who appear as witnesses are entitled to voice opinions—other than those who are officers of the Commonwealth, of course. I think, however, it's incumbent on us to correct a few misunderstandings and facts that have been voiced during the day in terms of the opportunity to correct facts. I'm happy, once we check that the patient details have been de-identified—although they are largely de-identified by the time we get them. That's my scrawl on this example. This form is the special access B form, and the overwhelming number are, depending on whether you want to print it two-sided or whatever, one and a third pages. Generally there are no attachments.

We have heard today that there's a need for a patient declaration on informed consent. That's not part of this form or our requirement. The actual information—which is largely the doctor's address and the patient's details—about previous medicines tried and justification is eight, nine or maybe, if they're very wordy, 10 column-centimetres, or 100 words or so. This is one for chronic neuropathic pain. It's not, for example, one for paediatric epilepsy, where the evidence is extremely strong. The evidence about pain is still contested in many areas. This is one that was approved last week, for example.

Secondly, I want to clarify: it's not required that all other options have been exhausted. This is the Special Access Scheme for unapproved medicines. The law of the land is such that because these medicines are unapproved they haven't been evaluated for safety, quality and efficacy. Indeed, most medicinal cannabis products that are coming into Australia have not been assessed for safety, quality and efficacy by anyone. We do have requirements for quality, such as a TGO 93 declaration. Because of that, there is the requirement in law that they have to explain what they've tried, and it would generally not be seen as first line. We have heard today incorrectly that this scheme is only for if every other single medicine has been exhausted.

The other thing is that it has also been asserted that this whole scheme was created for medicinal cannabis, or it was shoehorned into the scheme. For medicinal cannabis, as people have talked about, there were about 30,000 or 25,000 special access B last year, but the total number of Special Access Scheme last year was 105,000, so it still only represents a minority of the total amount of the Special Access Scheme. This is a scheme that's been going for a long period of time and is used extensively for unapproved medicines. This form is available online and is cloned. If a medicine is out of stock, a new form does have to go in electronically and is looked at within 48 hours—generally much faster than that. They would need to replace these one or two boxes down here with the names of the replacement medicines. It's a cloned form, so it's retained on the site. In that sense, it's been streamlined. As I say, our service standard is that everyone is done within two working days.

Senator BILYK: Is that standard always met?

Dr Skerritt: To my knowledge. There are some times where there might be some public holiday you've never heard of in the Northern Territory or in Queensland inconsistent with Commonwealth public holidays. But it's two working days for both jurisdictions.

That leads me onto the other comment: why are the states required to be involved at all? State approvals do apply for S8 drugs, so it's not true to say that there is absolutely no control over a GP or anyone else trying to get a prescription for an opiate or a schedule 8 drug. There are state requirements in many states about the maximum dose that can be prescribed. I think in all states there are rules about the total duration; if you exceed eight weeks or two months, state authorities are required to be given. Then there's a check that the patient does not have a drug dependency. Those checks do apply for other drugs, whether they're opiates or other schedule 8 drugs, as well as schedule 8 THC.

One of the other things to clarify is around clinical trials. There are at least a dozen—perhaps as many as 20—commercial clinical trials of cannabis products underway in Australia. These are with the expectation that they will seek ARTG approval, which has always been the way because that's a pathway to the Pharmaceutical Benefits Scheme. We heard earlier that in March the drug for multiple sclerosis is coming up again to the Pharmaceutical Benefits Scheme. We cannot disclose the list of products before us. But, because the company has disclosed to the stock exchange, we can disclose that there's a cannabis based drug for epilepsy that's also been submitted to TGA for review.

The other thing we've perhaps heard some confusion about today is plant extracts. We've got eight or nine examples of where TGA has registered a medicine that is actually a mixture of plant extracts. There's nothing magic about using a drug that is an extract of a plant. It has to be standardised; it can't vary dose to dose. You always have the same ratios of things in that plant extract. We've already got one cannabis drug like that on the register—Sativex for multiple sclerosis—and for a range of other conditions there are about eight or nine other drugs. So there's nothing that stops that sort of thing, the same way that there's nothing that stops—as we heard some of the others say—use of either an accelerated approval based on an overseas regulator's review, the potential to apply for a provisional pathway where more evidence is gained while the product is on the market and those patients are monitored, or indeed other pathways, such as using a literature based submission.

Finally, there are different security requirements for THC and cannabidiol crops. Again, commercial confidentiality requirements mean I can't go into details because it may identify particular sites and locations, and policy is that we don't disclose names and addresses. For example, at a site that only applies to grow cannabidiol crops—these can be indoor or outdoor, but if it's outdoor it may have one layer of high fencing—they can incinerate or compost their crops on site. If it's high THC, they have to have additional security measures—it might be two layers of fencing; it might be security cameras; it might be 24-hour monitoring—and they actually have to account for all the crops that are unused and discarded. So there are already different requirements for CBD and THC crops.

There is an issue in international law about whether hemp crops, industrial hemp as we heard the previous speakers say, can use those crops, and I'm happy to go into that in more detail if senators wish. I would add that the Narcotic Drugs Amendment Act, when it was introduced and passed through the parliament in 2016, had a highly risk-averse posture. That's not an opinion expressed by a public servant, but the view, which has been endorsed by government, of the external review of our narcotic drugs act. So Professor McMillan, former Australian ombudsman, completed a review in July last year. The government has accepted all of the recommendations in principle and has already amended certain regulations under the existing act. It has also made a public commitment to introduce legislation into parliament, hopefully by midyear, to amend the act to take a lot of the unnecessary regulatory burden out of it and to adopt a more liberal posture, because it was highly risk-averse.

Finally, I do want to make one point clear. There has been a lot said today about the International Narcotics Control Board and this term 'scheduling' that they use. It is quite a different issue from what we in Australia call scheduling. There has been a lot of confusion and some misunderstanding about that, including from senators. So the United Nations Commission on Narcotic Drugs has this WHO recommendation to take cannabidiol out of the class of schedules, as they said, as drugs of dependence. There may well be implications for how hemp can be handled as a result of that, but I would remind senators that that has not yet gone—it has been deferred twice, for reasons outside our control, for discussion in the United Nations forum. It may be discussed this March—that's still to be confirmed—and, no, we do not know what the Australian government official position is on that. But that is about whether cannabidiol is or isn't a drug of dependence.

Now, in Australia, we actually took it out of the—we have schedules. Medicines are unscheduled, or schedule 2, 3, 4, 8 or 9. We took cannabidiol down to schedule 4, if it's sufficiently pure, because it wasn't a drug of dependence. In a way, we were actually ahead of WHO by a couple of years there. And while that may have implications for how hemp is handled that does not relate to whether scheduling, for example, low-dose cannabidiol products could be considered for over-the-counter use. That's something that could be considered at any time in response to an application. I'll leave it there, but I just wanted to clarify a few areas of misunderstanding.

CHAIR: Thank you.

Senator URQUHART: Thank you for your clarification of some of those points. I just want to go to a couple of areas in your submission. You say, on page 13, that over 18,000 patients have accessed the medicinal cannabis legally. That's obviously very welcome, but do you acknowledge that there is still an unmet demand?

Dr Skerritt: It's not the role of a regulator to assess demand for a product. We don't go out and say, 'Hmm, there's a new drug for breast cancer and there are 5,000, 10,000 or 520,000 patients.' We believe that demand is determined by the patient-doctor discussion. So we don't have a position on what demand is for any particular drug.

Senator URQUHART: So you haven't analysed or modelled the extent of that demand or how many people are actually missing out?

Dr Skerritt: No. Well, the phrase 'missing out' is subjective, but we don't have an idea of the number of patients who would like—again, it comes down to do you say, 'Is this the number of patients who'd like to have access to medicinal cannabis, or the number of doctors who'd like to prescribe it?' At the end of the day, our role is to enable products to be available. In the case of unapproved medicines, our role is additional controls to check what they're prescribing is appropriate. In about five per cent of cases, we return the SAS B application because we have questions about it.

Senator URQUHART: The Lambert initiative estimated that only three per cent of people using medicinal cannabis in Australia are able to do so legally, which means that up to 600,000 people are missing out on legal access. Do you have any comments on those estimates?

Dr Skerritt: No. We have no way of knowing how those figures were obtained.

Senator URQUHART: Do you contest those numbers?

Dr Skerritt: We have no way of knowing whether they're correct or incorrect.

Senator URQUHART: Putting aside that number then, what are the key barriers to accessing legal medicinal cannabis as of today?

Dr Skerritt: I think the main issues have been raised throughout the submissions and throughout the testimonies today. Clearly, when a medicine—and it doesn't matter whether it's cannabis or a cancer medicine or even a range of other medicines—is not PBS reimbursed, it means that, for those who are of challenging means, the cost is a significant factor. The cost of medicinal cannabis does vary tremendously. Some of the low-dose THC products are as little as \$5 to \$6 a day. That's still a lot if you're on a pension, but if you're in a good job, like all of us here, that's affordable. The challenge is for the children, especially the larger children, who are on the cannabidiol medicines for epilepsy, because the amount of cannabidiol used for each child—the actual quantity, the size of pill—is quite large. The cost, as we've heard today, can run into the thousands of dollars a month.

Senator URQUHART: So would cost be the key barrier that you see?

Dr Skerritt: The various ones—cost, doctor education. But, at the end of the day, there's a link between education and evidence. The evidence varies in strength depending on the condition or indication. There would be few doctors, for example, who specialise in epilepsy who would not be satisfied with the quality of the data supporting the use of medicinal cannabis products as an adjunct in certain genetic epilepsies in children; the evidence is quite strong. It's quite contested in other areas like pain, for example.

Senator URQUHART: Can you talk me through what the government is doing to address those issues such as cost and doctor education. What role is the government undertaking in those areas?

Dr Skerritt: The policy of the government is to encourage more and more of these products to be TGA registered and for the companies then to seek reimbursement through the Pharmaceutical Benefits Scheme. It does appear that we've developed two broad commercial models. Some companies are clearly not expressing interest in producing registered pharmaceutical medicines. Others, as indicated by the 12 to 20 commercial clinical trials—and I say 12 to 20 because some of the them are partnerships with academia—clearly have a priority of getting products on the TGA register and then, hopefully, on the Pharmaceutical Benefits Scheme.

Senator URQUHART: So is that simply what the role of government is at this stage?

Dr Skerritt: State and territory governments have also been quite active in funding a range of compassionate access schemes. There are a range of schemes, and we're happy to provide our summary of those on notice. While they vary in the number of patients that they can target, many of them have indeed targeted the patients of greatest need, such as kids with serious epilepsies.

Senator URQUHART: It would be useful if you could provide the state and territory stuff on notice. Just to go to the states, in your submission, on page 21, you've got the documentation that shows that there are no authorised prescribers in South Australia, Tasmania, the ACT and the Northern Territory. Is that still the case? I think that was as of 2019.

Dr Skerritt: Yes. There are two issues. Firstly, the term 'authorised prescriber' has often been used incorrectly in the media. Remember there are two broad approaches to accessing an unapproved medicine. The first is the

Special Access Scheme, where you do it patient by patient. The second is broad authorisation. We had expected that the majority of medicinal cannabis would come through a large number of authorised prescribers when the scheme came out, but we can't say to a doctor, 'You must become an authorised prescriber.' We have some doctors who may have prescribed—I don't know, Grant?—50, 100 or more SAS applications, and they say to us: 'Well, I can clone them now. It's easy. It's just a couple of keystrokes. I couldn't be bothered becoming an authorised prescriber.'

Senator URQUHART: In Tasmania, where Senators Askew and Bilyk and I are from, we've got a state government who hasn't signed up to that streamlining process that they need to go through. Why have they not done that and what assistance has the Australian government given those states to do that?

Dr Skerritt: COAG health ministers did discuss this. Minister Hunt strongly urged other health ministers to come on board with the scheme. Tasmania made their sovereign choice not to take part in the scheme.

Senator URQUHART: Can you tell me why they made that choice? What was their rationale?

Dr Skerritt: I wasn't in the room for those discussions. They believe that the system of, on the one hand, strictly limiting the number of patients but, on the other hand, funding every single one of the 17 or so patients was the best. That was the view of the Tasmanian government.

Senator BILYK: Where did that number of 17 come from?

Dr Skerritt: We believe that there have been 17 patients who have been supported in Tasmania only.

Senator BILYK: Seventeen patients, not 17 applications?

Dr Skerritt: Seventeen patients. I think the number of applications is higher. That figure is in the public domain.

Senator BILYK: And that's through specialists?

Dr Skerritt: In Tasmania, they're the only state that remains with the absolute requirement for specialists.

Dr Pegg: That's right.

Dr Skerritt: Thanks, Grant. Just checking.

Dr Pegg: Can I add something there? We also engaged heavily with Tasmania in the development of the streamlined online system.

Senator URQUHART: Okay. Tell me about that. Why aren't we doing it?

Dr Pegg: As you can imagine, it was quite a complex process engaging with every state and territory with their various requirements and building that into an IT system. Tasmania was part of that conversation but indicated they didn't want to be part of it and didn't really clearly articulate that to us. As John has indicated, that was mooted at COAG. The other thing I would mention is that if the Commonwealth were to receive an application from a patient in Tasmania we would assess it on its merits and approve it if it met the criteria. However—

Senator URQUHART: But it just makes the hurdles—

Dr Pegg: It would be moot because the state requirements are basically an agreement.

Senator URQUHART: So the impact on those patients in, say, Tasmania, even though they could go through that process, is an impact that they wouldn't really need to have if they lived in, say, Victoria or somewhere?

Dr Pegg: Correct.

Senator BILYK: So it's a postcode situation at the minute, isn't it?

Dr Pegg: The system as it stands, if a doctor in Tasmania is to make an application through—

Senator ASKEW: Can I clarify your comment earlier. Was it about the computer system? Was the expense of that the issue?

Dr Pegg: No, it was in the development of that, because each state and territory has different requirements. We had to build in, for want of a better word, a smart form in the back end of the system to, once a prescriber selected which state they were in, walk them through the requirements. That's why there was close consultation with the states and territories.

Senator URQUHART: I want to clarify—obviously these dates are when your submission was written—that there have been 12 SAS category B approvals in Tasmania, but you talked about 17, so I'm not sure what the difference there is, and five in the Northern Territory.

Dr Skerritt: It may be an issue of timing. Last I heard it was 17 in Tasmania. I remember it well. It was finalised on Boxing Day.

Senator URQUHART: Okay. So there are hardly going to be five since Boxing Day.

Dr Skerritt: There could have been five more. They might come through in clusters. I think the main point is that the number is disproportionately small compared with other east coast states.

Senator BILYK: Part of that might be that they have to actually go to a specialist, mightn't it?

Dr Skerritt: Yes.

Senator BILYK: And what if they can't afford it?

Dr Skerritt: These are requirements—believe it or not, we still have states, senators. The states do have their legal rights to be able to do this. We often get correspondence to say the Commonwealth should override the Tasmanians and this, that and the other. As much as it may be tempting, this business is perfectly within the legal pharmaceutical framework for the individual states and territories.

Senator URQUHART: Just in terms of that, then, is the Commonwealth working with the Tasmanian government to address that? Are both jurisdictions committed to fixing the problem in Tasmania?

Dr Skerritt: It depends on whether you identify it as a problem. I know that Minister Hunt—

Senator URQUHART: I'm sure the patients do.

Dr Skerritt: Yes. Minister Hunt has committed to raise it with Tasmania at every opportunity he has. There is another meeting of health ministers, I think, late in February. I would be surprised if he didn't raise it. Again, it is Tasmania's sovereign right to manage their scheme as they wish.

Senator BILYK: Sorry, Senator Urquhart, I need to clarify this: you said 12 as of Boxing Day—is that correct?

Dr Skerritt: We can clarify that on notice. We will clarify it with the chief pharmacist.

Senator BILYK: I'm a bit confused about whether it's 12 or 17.

Dr Skerritt: If I can take that on notice, we'll clarify it with the Chief Pharmacist of Tasmania.

Senator BILYK: I'm wondering whether the extra five are the Northern Territory ones.

Dr Skerritt: We can never give up-to-date numbers on medicinal cannabis when you have, nationally, 3½ thousand new ones every month. Every day we're always a couple of hundred out if we're reporting to senators and ministers.

Senator BILYK: Maybe you can take that on notice.

CHAIR: If you can clarify that. The point is that it's an exceedingly low number.

Dr Skerritt: It is.

Senator URQUHART: That's probably because of the process.

CHAIR: Exactly.

Senator URQUHART: Can you confirm that there are no clinical trials of medicinal cannabis in Tasmania or the Northern Territory?

Dr Skerritt: I would have to take that on notice. Most of them are in the other mainland states and territories. Most of the money for this is from companies in Victoria, New South Wales, Queensland and Western Australia, as well as the state governments, such as New South Wales, who have also funded clinical trials.

Senator URQUHART: In the table you've got on page 23, Tasmania and Northern Territory don't show at all. I'm trying to clarify that.

Dr Pegg: That would indicate that that is correct. To clarify, the data we hold with respect to clinical trials is a notification scheme. The trial sponsor notifies the TGA prior to commencement of the trial once all other various approvals are in place. They will nominate where their trial sites are. An extract of that is how we populated the table.

Senator URQUHART: So we can assume by that that there are none. What impact does that have for patients in Tasmania and the Northern Territory that there are no clinical trials?

Dr Skerritt: If they were to take part in a clinical trial they would have to travel interstate.

Senator URQUHART: So there's no opportunity for them to do that?

Dr Skerritt: Not in their home state. That's really the decision of either the public sector researchers or the private sector companies as to where they form partnerships to hold those roles.

Senator URQUHART: Would you agree then that there is significant variation between jurisdictions in access to medicinal cannabis, given that that's clearly—

Dr Skerritt: I think the facts show that there is a difference between jurisdictions in the number of SAS, Special Access Scheme. Again, we are responsive to that. We accept what we receive and also clinical trial notifications.

Senator URQUHART: It certainly undermines the concept of a national scheme, doesn't it, when you haven't got states and territories that are participating?

Dr Skerritt: It reflects two things. It reflects differences in the willingness of doctors to prescribe—for example, if you look at it demographically, there are differences that don't correlate with population, even for mainland states, and then you also look at where research groups and industry choose to form partnerships to establish clinical trials. If you took a particular group of cancer medicines, there would be some states and territories that would not have trial sites. This is a common problem. We often hear that if you've got cancer you have to be in Sydney and Melbourne to be in the clinical trials. The government has brought in a measure to encourage clinical trials—I'm now talking more broadly on clinical trials—in rural and remote areas, but it has been an ongoing challenge globally as far as access to clinical trials once you're outside major cities.

Senator URQUHART: Are you saying Hobart's not a major city?

CHAIR: Don't go there!

Dr Skerritt: I better not go there, Senator. In fact, if it's any comfort, I really like Hobart. I was in Hobart—

Senator URQUHART: It doesn't matter whether you like it or not; the fact is you can't get the treatment.

Dr Skerritt: Senator, I was in Hobart on Monday, two days ago. It really just determines where for the companies, the research and the hospital institutions.

Senator URQUHART: In your submission it tells us that the National Health and Medical Research Council has invested \$3.4 million in medicinal cannabis research over the last decade and that another \$3 million will shortly be available through the Medical Research Future Fund. Of course that's welcome, but would you agree that they're relatively small amounts?

Dr Skerritt: We don't have any influence on the relative quantum of funds for the NHMRC.

Senator URQUHART: What would be a normal amount for a trial of research?

Dr Skerritt: The trials vary hugely according to their size, whether they're observational trials or whether they're randomised. Research funding for a clinical trial can be a couple of hundred thousand up to many millions of dollars. I think it's fair to say that there's a reasonably dynamic group of clinical trials being done with industry funding and also with state and territory funding, as well as with funding from these sources. We actually have a link to the clinical trials that are current—not ones going back 10 years, but ones that were in the last few years, and many are still going—on the TGA website. They go into the dozens. You can see that the number of notifications, if you add them all up, also goes up to probably over 100.

Senator URQUHART: Would you agree that additional research would help build the evidence for medicinal cannabis and possibly strengthen ultimate TGA and PBS applications?

Dr Skerritt: Certainly—

Senator URQUHART: We've heard today that that's what's needed.

Dr Skerritt: but I'd also like to clarify that, especially in TGA registration—and, indeed, PBS—looking at the efficacy base we are not country specific. We look at evidence from all over the world. Many of our new medicines are reviewed and approved where most of the patients involved in the clinical trials have been based overseas. It's really looking at the quality of the data, not that they have been within our borders.

Senator URQUHART: Your submission acknowledges resourcing and processing challenges for the Office of Drug Control. Has the government made additional resources available to the ODC? We heard earlier that it's very underfunded and under-resourced, so has the government made any additional resources available?

Dr Skerritt: I'll pass over to my colleague Mr Masri, but, as we heard before, the original staffing of the Office of Drug Control was premised on a Deloitte's study that suggested that there were going to be only a handful of applications. Therefore, it wasn't a scalable funding model. If the TGA gets twice as many new medicine applications, the TGA gets twice as much funding. The model for the Office of Drug Control has the

money going into consolidated revenue and then, with a bit of a lag time, we have to apply for that funding based on the volumes we expect. Everyone was caught out. The volumes were much higher.

Senator URQUHART: So, having been caught out, has the government made additional resources available?

Mr Masri: There are a couple of factors to take into account. The government did provide to the ODC, in the context of the medicinal cannabis scheme, additional funds in the December 2018 MYEFO decision.

Senator URQUHART: How much was that?

Mr Masri: It amounted to a bit over \$5 million. It was a significant increase on what was the projected volume of work and the staffing requirement. What we're conducting presently—and we'll be shortly engaging with industry as part of our responsibility to consult around fees and charges—is an assessment of the work effort involved. In considering the work effort involved and, therefore, the resources we require, there are a few challenges. There is projecting further licence applications, the nature of the industry and the regulatory activity that we'll be focusing on. We're still getting 10 or 12 applications a month—we're close to 300 applications for licences. Then you have the permits and the compliance sort of work. We're factoring in that our regulatory focus will be moving from licence applications to permits, permit renewals, variations and, importantly, inspections and compliance.

Starting tomorrow in Melbourne and going to Brisbane on Friday and Sydney on Monday, we're about to provide some options as a starting point to talk about the fees and charges that we're likely to ask the government to agree to. We've got obligations, in relation to fees and charges, to be consistent with the Commonwealth government's framework on fees and charges. Effectively there are some options that we're looking at to ensure that we have a more agile and appropriate set of fees and charges that will actually reflect the effort involved in our regulatory function. We've had some quite constructive discussions with the Department of Finance charging area just to ensure that we're consistent. We're engaging with them around our obligations under the charging framework. We're confident that through this process we will get a better revenue source through a more appropriate fees and charges framework and that will give us then the right level of resourcing.

The other important thing is that, as Professor Skerritt mentioned, even though we don't have a special account, unlike the TGA, there are opportunities to review and adjust what we will get by way of revenue from industry to match our resource requirements. We have the benefit, I guess, of three-years-plus regulation. We've also got to factor in that there will be amendments to the legislation that will streamline some activity. We are factoring in some of that streamlining. We're factoring in business process improvements, we're removing duplication and we're making some internal improvements. I'm reasonably confident that we'll have a pretty good basis for the appropriate level of resourcing.

Senator URQUHART: I have a quick follow-on question. There was \$5 million in the MYEFO of 2018. Is that what you said?

Mr Masri: Yes, December—

Senator URQUHART: Were there any additional FTE staff? And was it additional money or was it offset within the department?

Mr Masri: It was additional money. One of the important principles of a charging framework is that the revenue we get from industry should be what we get by way of revenue to fund the regulatory function. That's the basic principle. We're anticipating the revenue we get from fees and charges. That was part of our submission—that the volume of licence applications and permits means that we get more revenue. One of the challenges has been that we were limited by the ASL cap—also within the department. We've had to resource a lot of the new staffing by way of contractors. That is a challenge. Contractors are very much part of the team—we train them and we support them—but there's a greater level of throughput because there are other opportunities for contractors.

Senator DI NATALE: I want to go to the numbers again. We're talking about 18,000 patients in total. Did I hear that number correctly? Just a ballpark—

Dr Skerritt: There are about 19½ thousand patients now. As has been said before, we do not trace through to the script being filled and dispensed. We have heard that there are cases where patients get sticker shock and don't fill the script. Increasingly, the clinicians we talk to have a discussion with patients about the likely cost of the product. It's a very different discussion—a doctor having a discussion with a patient about neuropathic pain and using a low-dose THC product compared to a discussion about a child with epilepsy, where you will need a very high amount of CBD.

Senator DI NATALE: Basically, just that so I'm clear, these are 18,000 unique patients—

Dr Skerritt: We believe there are over 19,000 unique patients.

Senator DI NATALE: Over 19,000—sorry. A total of 25,000 was bandied around. Some of those will be repeat scripts. Is that why—

Dr Skerritt: Some of those are repeat scripts—yes. There were 25,000 SAS Bs last year, roughly.

Senator DI NATALE: But 19,000 individuals, and of those a proportion will not have had their script filled because of cost. We don't know how many, and it's not your role to—

Dr Skerritt: It's not our role, although, increasingly, in communications with clinicians, clinical groups—they didn't say it today, but one of the things they say to our members is that, for any non-PBS medicine, and it's been the same when I've been prescribed a non-PBS medicine, the doctor says it's going to cost \$150 a month.

Senator DI NATALE: It depends on which doctor you see. We heard from the pharmacists. The pharmacists said to us that there are a number of patients who go there and say, 'Sorry, we're not paying for it.' That's the unknown, as far as we can tell. Did I hear correctly that you said there are 100,000 Special Access Scheme scripts—

Dr Skerritt: There are over 100,000 Special Access Scheme applications and notifications a year. Medicinal cannabis is only a proportion.

Senator DI NATALE: Maybe one-fifth of that.

Dr Skerritt: Maybe a bit more.

Senator DI NATALE: Okay. A quarter, if there are 25,000 scripts—

Dr Skerritt: Last calendar year—

Senator DI NATALE: So it's a quarter. Do any other drugs represent as big a proportion?

Dr Skerritt: No, but remember that medicinal cannabis products, as we've heard today, are not one product. They're also a cluster—

Senator DI NATALE: I get that, but we're talking about medicinal cannabis products. What's the next biggest unregistered drug through the Special Access Scheme?

Dr Pegg: We'd have to take that on notice.

Senator DI NATALE: Would one drug come close to representing a quarter of the Special—

Dr Pegg: No.

Senator DI NATALE: I would imagine you're talking about lots and lots of very different drugs and that maybe, at most, 1,000 or 2,000 might be represented by one drug.

Dr Skerritt: There are some that number a couple of thousand. Why we're a bit hesitant is that it varies dramatically by year. Often there will be a big burst of Special Access Scheme requests and then, with a bit of encouragement, a company will register it and it will disappear from the Special Access Scheme. We're happy to take, say, SAS B requests—

Senator DI NATALE: Yes, but it's a safe assumption to say medicinal cannabis is, by far and away, as a drug category—

Dr Skerritt: Well, we'll have a cluster. But there are quite a few antibiotics, for example, that are no longer registered in Australia, so there'd be a large number of them too.

Senator DI NATALE: What's the purpose of the Special Access Scheme?

Dr Skerritt: Well, the overall scheme is these products are unapproved, so they haven't been through TGA assessment for quality, safety and efficacy. Generally, the other Special Access Scheme drugs, such as those on Special Access Scheme C, have a long history. They might have been in the German and French markets for 20 years and the Australian market's too small.

Senator DI NATALE: I'm going to come to that in a moment.

Dr Skerritt: With medicinal cannabis, we actually don't have that. With those particular products we don't have that history of use anywhere in the world, regarding evidence of quality, safety and efficacy in the long run, so there are additional unknowns with medicinal cannabis compared even with many of the other drugs on the Special Access Scheme.

Senator DI NATALE: Do you feel that the fact that more patients are getting access is a good thing now through the Special Access Scheme?

Dr Skerritt: You've asked me for an opinion, Senator. We respond to demand. If 200,000 applied next year, 200,000 apply; if five applied next year, five apply.

Senator DI NATALE: Your job, though, is to test for safety and efficacy, isn't it?

Dr Skerritt: Our job, eventually, is to encourage—

Senator DI NATALE: That's the job of the regulator, isn't it?

Dr Skerritt: as many products as possible to go through the application process to be assessed against safety, quality and efficacy. So we're absolutely delighted, although we'll assess it on its merits, that there are other drugs now—cannabis based drugs—that are coming into TGA for—

Senator DI NATALE: Well, there's one.

Dr Skerritt: There's one that I've mentioned.

Senator DI NATALE: And it costs thousands of dollars. My point is: you're a regulator whose purpose is to assess safety and efficacy.

Dr Skerritt: And quality.

Senator DI NATALE: And quality. Yet every time we have this discussion through estimates you're very keen to tell us about the numbers of patients who have been prescribed medicinal cannabis through the Special Access Scheme, which is effectively a scheme that bypasses your role to assess safety and efficacy.

Dr Skerritt: Regulators globally have similar schemes.

Senator DI NATALE: That's not my point.

Dr Skerritt: But, Senator, if I could explain the policy intent—I think that's the role of an official. Regulators globally have similar schemes to the Special Access Scheme. They recognise that there may be medicines or groups of medicines that, because the market is small, the market is new or for other reasons, are not on the market either yet or at any one time—we've talked about the old French and German antibiotics, for example—and yet patients still have requirements for them, and the regulator has a role, and it varies by country, depending on their legislation. We have a role, therefore, in checking that these products are of appropriate quality, because they have to meet the TGO 93. We have a role to check under SAS B that the indications are appropriate. And, while 95 per cent go through, it's not 100 per cent that go through—

Senator DI NATALE: But these are drugs not assessed for efficacy, safety and quality in the way that you assess other drugs that are approved.

Dr Skerritt: They're not assessed as for registered medicines.

Senator DI NATALE: And yet we've got a big and growing number of products through a pathway that bypasses your central function, which is to assess products for safety, quality and efficacy. And every time we have this conversation that number keeps growing and growing, and, based on the trajectory we are on, we are looking at significant multiples of what we've got at the moment with people on a category of drugs that won't have been assessed for the functions that you exist to assess for.

Dr Skerritt: They're assessed for quality. Our ambition is that—

Senator DI NATALE: Sorry, let's be clear about this: they're assessed for quality.

Dr Skerritt: They're assessed for quality in terms of the requirement to meet Therapeutic Goods Order 93.

Senator DI NATALE: What does that mean? Let's be clear about this compared to what it means to get on the register.

Dr Skerritt: Therapeutic Goods Order 93 is a quality order. It's a legal instrument that goes into the content of THC and CBD having to be as declared. It goes into heavy metals. It goes into fungal and bacterial contamination, because there have been deaths—for example, in California—due to fungal contamination.

Senator DI NATALE: How do you assess those things?

Dr Skerritt: It is on declaration, but—

Senator DI NATALE: Do you test? Do you do any testing—

Dr Skerritt: We do.

Senator DI NATALE: or is it based on—

Dr Skerritt: It's on both. There's declaration, but we do do testing.

Senator DI NATALE: What proportion are tested?

Dr Skerritt: I'd have to take that on notice.

Senator DI NATALE: Less than one per cent?

Dr Skerritt: It's more than that. We don't test every batch, but we do check if there are problems or issues reported to us.

Senator DI NATALE: But not for safety, which is one of the things that has come up time and time again.

Dr Skerritt: No, our check for safety is when we receive the thing I waved around at the beginning.

Senator DI NATALE: That's a separate matter. I want to be clear: this is a very technical area, and it's very easy to confuse people.

Dr Skerritt: I'm the regulator talking to you about safety. We check for safety. For example, we had a toddler who was prescribed a specific medicinal cannabis product as a sleeping aid. We questioned the safety of that in a young toddler, and we've acted on that.

Senator DI NATALE: On a drug that hasn't been assessed for safety?

Dr Skerritt: On a medicinal cannabis product.

Senator DI NATALE: But it has not been assessed for safety. That's my central argument.

Dr Skerritt: That's why our ambition is that as many of these products as possible end up on the Australian Register of Therapeutic Goods.

Senator DI NATALE: But it's not happening. The opposite is happening. We are seeing an increasing number of people being prescribed a drug through a scheme that exists to bypass an assessment of safety, quality and efficacy based on your acts.

Dr Skerritt: I think you have to be patient. These clinical trials have only just started over the last couple of years.

Senator DI NATALE: I've been at this for five years; I've been very patient. I've been speaking to people whose kids are having fits. I've spoken to people who are puking their guts out because they can't access a simple, straightforward drug that they should be able to access legally. So don't tell me to be patient. I'm very patient, but I'm running out of patience.

Dr Skerritt: But the initial clinical trials—for example, ones supported by New South Wales or by Queensland—started less than three years ago. You know the time it takes from commencement of clinical trials through to the reporting.

Senator DI NATALE: We've just heard that in Canada that the market is 18 years old.

Dr Skerritt: Yes, it's 18 years old. Our uptake of medicinal cannabis is actually faster than it was in the first few years of the Canadian scheme, as we say in our submission.

Senator DI NATALE: Your uptake is through a scheme that bypasses what you do. Do you understand my point?

Dr Skerritt: This is a scheme for medicines that are not registered.

Senator DI NATALE: That's right.

Dr Skerritt: Is the alternative that we do not have a scheme at all?

Senator DI NATALE: They're not registered for safety, quality and efficacy. This comes up every time we meet through Senate estimates. You've got the numbers there. We've had an extra 3,000 people through the scheme. We've just heard again that we're up to 19,000 people—only 17 in Tasmania. It's terrible. People are accessing a drug via a pathway that bypasses what you exist to do. Doesn't that say to you that there's something wrong with the scheme?

Dr Skerritt: I do not agree with your assertion that it bypasses in full. Our role—why we have an SAS B—is to look at signals for safety about particular patients. That's where we go back to the clinician and say: 'We think your dose is 10 times too high. You shouldn't be giving this to a toddler.'

Senator DI NATALE: But the drug itself hasn't been assessed for safety. You're making an assessment of safety on a drug that hasn't been assessed for safety.

Dr Skerritt: As we've heard throughout today, there is a reasonable amount known about the clinical safety of THC and CBD. That's different from assessment of a finished product. But we have clinical literature on the safety or otherwise of low, medium and high doses of THC, CBD and otherwise. This is why we can feel that there would be limited adverse events for a low dose of CBD, for example, going into almost any patient and why we might have some signals and concerns raised of a high dose of THC being given to a toddler. I think I've moved into a different universe if we're now asserting that there's not anything known about the safety of THC or

CBD. However, these products have not been through as finished products, and that is the ambition. That is why the schemes exist, and, quite often once there are a large number of drugs that come through the Special Access Scheme, the next step is that they apply for TGA registration.

Senator DI NATALE: You've said that you couldn't talk about specific drugs. How many drugs are currently before you with an application for registration?

Dr Skerritt: I can talk about the GW Pharmaceuticals product—because they've announced it to the stock exchange—Epidiolex.

Senator DI NATALE: You can't talk in general terms about the number of drugs—

Dr Skerritt: I can't confirm or deny numbers, and that's the same for any pharmaceutical application. That's government policy.

Senator DI NATALE: So we can't have a sense of this—we're talking about categories; we're not talking about individual drugs.

Dr Skerritt: We can't disclose categories.

Senator DI NATALE: All right. Let's go to a few other issues. Again, you come at this from the perspective of a regulator. I come at it from the perspective of someone who has worked as a GP and who has spoken to patients. You gave the argument of opiates and that there are state requirements for the prescription of opiates. I'm not sure what argument you were trying to make there.

Dr Skerritt: I rebutted the assertion that you'd made because I thought it was an incorrect assertion that there were 'no controls' for GP prescriptions over opiates.

Senator DI NATALE: No, I didn't—maybe I was paraphrasing. But the point is that I can write a script, provided that it conforms with the appropriate dosages. A specialist in Tasmania is not going to step in and monitor my script for an opiate and say I can't prescribe it. Isn't that the case?

Dr Skerritt: It is if your duration is limited to under eight weeks in most states, if your dose is limited in most states, and if your patient does not have a history of drug dependence. That is why all states have a record of S8 prescribing and rules around schedule 8 prescribing. For example, in some states you have to do it in handwriting.

Senator DI NATALE: Sure, there are a number of requirements around prescribing the drug. My point is that as a GP I can prescribe it. I don't need to get special permission from you—

Dr Skerritt: It's because these drugs have been assessed by the TGA for safety, quality and efficacy.

Senator DI NATALE: Okay. Let's get to that then. What is the potential for overdose with any medicinal cannabis product compared with opiates such as Endone, Panadeine Forte and a range of others?

Dr Skerritt: Opiates have a much greater propensity for overdose; however, medicinal cannabis products are not without adverse events.

Senator DI NATALE: No, I'm talking about the potential for a fatal overdose.

Dr Skerritt: For fatal overdoses, it's much higher for opioids.

Senator DI NATALE: It's much higher.

Dr Skerritt: They're big killers.

Senator DI NATALE: How many people are you aware of who've died from a potential overdose of a medicinal cannabis product?

Dr Skerritt: I'm not aware of anyone who has directly, in a toxicological sense, died from an overdose of a medicinal cannabis product.

Senator DI NATALE: How many people in the US died last year from overdosing from opiates?

Dr Skerritt: I'd have to take the exact figure on notice.

Senator DI NATALE: I'll give you a ballpark. I think it's about 50,000 to 60,000 people.

Dr Skerritt: It depends whether you include fentanyl or—

Senator DI NATALE: Opiates—drugs which I can prescribe without any controls.

Dr Skerritt: Senator, my highest priority as the head of the TGA is to reduce Australian overdose deaths from opioids. To me that is my No. 1 priority.

Senator DI NATALE: I'll tell you what: have a look at some of the evidence that is emerging from the States, where medicinal cannabis is being prescribed, and you'll see a significant substitution effect and a reduction in overdose mortality from opiates.

Dr Skerritt: The evidence on that is sadly contested. The studies show, if you look at a state level where there have been strong medicinal cannabis schemes, that there are fewer deaths due to prescription opioids. But those states also tend to have good methadone and Suboxone programs, so they have good addiction-management programs as well. I'm not a drug policy researcher, but the cause-and-effect issue is still being debated. If we, for even one patient, could get someone off opioids and onto a suitable medicinal cannabis product, that would be a good thing. But I think it is still an area among drug policy people that is hotly debated—whether there is a direct substitution of people at the population level off opioids and onto medicinal cannabis—because of these confounding factors.

Senator DI NATALE: You might on notice want to review the evidence on this specific issue.

Dr Skerritt: I'm happy to provide you with references to half-a-dozen papers on that subject.

CHAIR: That would be appreciated.

Senator DI NATALE: Great. Excellent. The other issue that I think you raised was the issue of the scheduling of drugs. I think there might be a bit of confusion here. My understanding of the evidence provided from a number of witnesses was that, in relation to the Single Convention on Narcotic Drugs and the vote that's happening on CBD—and we don't know when that's going to happen—if in fact CBD is removed then the impact, while not direct, would be that it would provide more evidence for a change to the scheduling around CBD from schedule 4. I think that's the argument that's been made—

Dr Skerritt: I don't agree.

Senator DI NATALE: It provides another reason to change the scheduling of CBD here in Australia.

Dr Skerritt: Not if you look at the law of the land. Scheduling is determined by a thing known as a scheduling policy framework. A schedule 8 drug is something with a propensity for abuse, diversion and control. A schedule 4 drug, which cannabidiol is already, is not associated with a propensity for abuse. In the rescheduling of cannabidiol from schedule 8 to schedule 4—in a way, that's already happened.

Senator DI NATALE: I understand that, but the point I'm making is that it's another statement made by the international community that we don't think this drug is a harmful drug.

Dr Skerritt: I agree with your assertion there. Where I think we can flavour things is that several speakers asked—and we, indeed, raised it in our submission—whether it is appropriate for low-dose cannabidiol products to have to be a prescription, pharmaceutical or not. We're currently doing a literature review, and it is possible that that question will go out to public consultation.

Senator DI NATALE: Okay, that's encouraging.

Dr Skerritt: Should low-dose cannabidiol be available, for example, through pharmacies rather than on a doctor's prescription? But we're a couple of months away from that, and it would be an extensive public consultation because, as was highlighted earlier, there will be hundreds and hundreds of submissions with a wide diversity of views.

Senator DI NATALE: Yes. That's a shift, as far as I can tell.

Dr Skerritt: Well, the whole thing has shifted. It wasn't so many years ago that all these products were in the prohibited schedule, schedule 9. It's happening with cannabis, but it's almost the history of every single medicine over the last 50 years. If you take ibuprofen, it's very common. You can buy it at the 7-Eleven. That started off as a prescription medicine in Australia, and then, as we got familiar with its safety—it's comparatively low risk, although it does have some side effects—it moved down to being pharmacist only, and then they said, 'No, you don't need the pharmacist.' So this is a common pattern.

Senator DI NATALE: It's an encouraging pattern.

Dr Skerritt: Medicines move down from prescription only to over the counter. I can't predict what will happen and what the decision will be, but I wouldn't be surprised, as we've put in our formal submission, if there were a public discussion, with formal public consultation, submissions published, transparency and going to an advisory committee of experts and state and territory reps for their view.

CHAIR: What do you expect the time line for that to be?

Dr Skerritt: We, of our own volition, are doing a study that will be completed in March. We're happy to make the results of that study available. We will then ask the committee and get their advice, and I expect that they will say, 'Let's put it out to public consultation.' So it won't be until that study is complete and we have the discussion with the committee, but it would be during the course of calendar year 2020.

Senator DI NATALE: There was another thing that you said about GPs continuing to use the approval process for the Special Access Scheme rather than becoming authorised prescribers. I think the words you said were that they 'couldn't be bothered'. I want to understand what's involved to become an authorised prescriber. Am I correct in saying that you have to have either approval from a medical college or ethics approval?

Dr Skerritt: That's the approach. Again, my colleague Dr Pegg can explain a bit more. It was a little bit misconstrued earlier, that there was then a second round of approvals by TGA. Our role is more to check that the submission is complete. But the fundamental thing is approval by either the college or the ethics committee.

Dr Pegg: That's right. From the TGA end, it's essentially a regulatory check. The one example, perhaps, where there's a bit of nuance is in the cannabis clinic space, because the intent of the scheme is for patients under your direct care, and that model is potentially like a referral model, where a GP might refer. So sometimes it's not about a no or a rejection; it's more about tweaking some of those conditions.

Senator DI NATALE: Are most cannabis clinic doctors authorised prescribers?

Dr Pegg: There's a mixture. But we find that, as there's increasing familiarity with the SAS online system, what we're told by the prescribers who use it is that they prefer it, because the cloning function is something that they can—

Senator DI NATALE: Sure, but it's still a burden. You can argue about how much of a burden it is, but often for GPs a minute extra per patient is significant. But, if you can make your life easier, why wouldn't you, as a one-off, become an authorised prescriber? Your view was that they couldn't be bothered. I'm trying to understand. That doesn't make sense to me, given that you have to go through an ethics approval process or have a college approve it. I understand the College of General Practitioners and the College of Physicians won't approve it. So then you need an ethics approval. What's involved in an ethics approval for authorised prescriber status?

Dr Skerritt: As you know, many GPs—not all—especially if they're specialists or fellows of RACGP, have affiliations with particular hospitals and even universities.

Senator DI NATALE: Most don't.

Dr Skerritt: Many don't.

Senator DI NATALE: Most.

Dr Skerritt: So that is a challenge for them, and that's why we had hoped the colleges would. Those colleges you mentioned have taken the view that they don't have the resources and they don't really have a research ethics role. We can't force them to do it, so sadly they are not doing it at the moment.

Senator DI NATALE: Isn't it possible to create a separate approach?

Dr Skerritt: The act could be changed to do that.

Senator DI NATALE: The example is that to become a methadone prescriber you've got to attend an accredited course.

Dr Skerritt: You would have to require a change to, I think, section 19 of the Therapeutic Goods Act.

Senator DI NATALE: Is a legislative change required?

Dr Skerritt: It's a legislative change, yes. To go back to why doctors are finding this easy: let's say you're a GP who specialises in pain; all this down here—the product that you've got familiar with for neuropathic pain—is all filled in. This is probably coming cut and paste out of the clinical notes from the discussion you've had with your patient. They can just cut and paste it across. That's why a lot of them are finding it pretty easy. So whether it's the scheme for the future or whether there is a need—it's not our decision; it's a decision of parliament, of course—to change the act to have a different form of authorised prescriber scheme is really up to the parliament.

Senator DI NATALE: And you don't have an opinion on what that—

Dr Skerritt: I'm an official; I don't have an opinion, Senator.

CHAIR: Have you provided advice to government on that?

Dr Skerritt: I don't know if I'd describe it as advice to government. I think there was corro where someone said, 'Can we alter the authorised prescriber scheme?' and I think we did say, 'It would require an act change.' So, as part of the corro response, we did. It wasn't a formal 'Here is a ministerial briefing on everything you wanted to know' but I do believe that in draft corro—and, of course, the final corro is under the hand of the minister's advisers and all that—we did explain that it would require a change to the act if the authorised prescriber scheme were changed. I just want it correct on the record.

Senator DI NATALE: I'm thinking again of the possible ways through both the education problem and the authorised prescriber problem. Would it be possible to administer a scheme where, to become an authorised prescriber, you've got to satisfy an accredited two-day program? That way you'd have dealt with the education component.

Dr Skerritt: Again, anything is possible if the parliament is minded to amend the act.

Senator DI NATALE: You don't see any obstacles in anything like that?

Dr Skerritt: Only one called parliament.

Senator DI NATALE: Okay. That's a small one. There was the issue we heard about from the Lambert crew, which was around getting access to data from the TGA. They'd found it was very difficult to get access to data. Particularly, they would have benefited from real-time information.

Dr Skerritt: The government announced in MYEFO that a small amount of money is now being made available—I think it was \$3½ million this year and \$6.6 next year—to partly cover a range of functions for which TGA wasn't funded. One of the challenges with TGA's fully-industry-cost-recovered model is that there are a number of functions, and they go into the tens of millions of dollars, for which we can't really directly charge people. We don't want to charge doctors or patients under the Special Access Scheme. We've heard enough about the financial impost. So that has been one of those things that we've had to absorb. For all the work to date, until very recently—everything we did on the Special Access Scheme, and I've got a list of about 10 other things that I can rattle off—we've had to squirrel away funds. We haven't had the resources, frankly, to provide as much disaggregated information as some groups would like. That's why, essentially, they've had to go through the formal process of requesting it under freedom of information.

We now do have a little bit of government support to cover off some of the costs of the Special Access Scheme, and some of the things, like medicine shortages, we heard about today, and things like orphan drugs—and I could go on. The government will continue to look at our cost-recovery model over the years to come, but the challenge was simply one of resources. It's nice to put up a whole lot of analyses of every scheme we do—you've asked about what other antibiotics and other things we do—but all that requires staff time and is a little bit discretionary, rather than the key focus of getting these things reviewed and out to doctors and patients. That's why they had to ask for that data under freedom of information.

Senator DI NATALE: Far be it from me to provide advice, but, given the amount of interest in this issue within the community, obviously the more information that's publicly available the more informed some of these decisions will be.

Dr Skerritt: I think now there's a small amount, and I've got to make sure I don't commit Dr Pegg and his team to a massive amount of work, but I think, now there's a little bit more funding, we can do a bit more. For example, another thing is that we realise it's two years since those clinical guidance documents came out. There has been not a flood but a trickle of some new studies, reports, out on clinical effects in different conditions. We'll use some of that funding to support an update of reporting on those studies, and we'll put all that up on our website.

Senator DI NATALE: A final question, which relates to resourcing but is a question for the Office of Drug Control. We heard time and time again through all the submissions—this is not a criticism of you personally—that you just don't have all the people and financial support to do what you need to do, to do the job. I get that's a question as much for the government as much as for you. What's going to change?

Mr Masri: A couple of things: I guess you've got to look at this in the context of the new scheme that started three years ago, but the nature of—

Senator DI NATALE: In some people's opinion, three years doesn't make something new.

Mr Masri: Yes, but the regulatory scheme had applicants who weren't familiar, I guess, with the requirements under the act and the regulations. On applications that were made, we could have made decisions early on in the piece to refuse applications, but the approach was taken to work with industry to ensure that the right information has come into play.

A couple of factors that will determine our resourcing and our capacity to deal with backlogs and to ensure that the industry is well regulated go to some of the issues that were in the McMillan report that go to the restrictive and prescriptive nature of the legislation being a big factor in our capacity to streamline some of the processes. In parallel to the review, we undertook some internal assessment of our organisational structure, our business processes, looking at the risk appetite and also looking at where we needed to focus our regulatory attention. All those factors need to be taken into account when you're looking at resources. I'm pretty confident, as I said earlier,

that the process we're going through, and we'll be looking to government around the budget process, will give us the right level of resourcing. So we've got to match our fees and charges that we're seeking from industry to the resources that we need to undertake our regulatory function.

Dr Skerritt: I'd just add that a really important step will be amendments to the Narcotic Drugs Act. Our bid has A status, which, as you know, has a reasonably high priority for introduction, maybe not in the autumn sittings but mid-year. It aims to take a lot of the unnecessary, risk-averse stuff that the parliament put in the initial amendments to the Narcotic Drugs Act—20/20 hindsight is a great thing. We heard from the industry players who were speaking before us about the complexity of having three licences—one for research, one for manufacture, one for cultivation. It was a good idea at the time, and they all supported it at the time—

Senator DI NATALE: No, it wasn't. No, it was a bad idea. We told you at the time it was a bad idea.

Dr Skerritt: One of the central things that are being consulted on at the moment is to say: 'Let's have a bit of flexibility. Let's just have one type of licence that can cover a range of different activities.' That will give the burgeoning industry in Australia a lot more flexibility and take out a lot of the 'Sorry, guys, you've got to now submit a whole new licence application because you're moving from research into cultivation'. Apart from the additional resources and the internal business processes, we're counting the days until, hopefully, the act is amended to take out some of this thing that we don't believe is really adding value. But when you have an act of parliament that says the secretary, or the decision-maker, 'must do dot, dot, dot', we have to do it, even if it's not a value-adding step.

Mr Masri: Also, in this legislation it's not only 'the secretary must have regard to', but the applicant must provide all this information. It is very prescriptive. We've removed some of those in the regulations that have come into force from 1 January—

Senator DI NATALE: I thought this government hated red tape.

Mr Masri: The amendments to the act will go further, I think, into reducing the mandatory requirements and information that we need to consider—applications that go into the hundreds and thousands of pages.

Dr Skerritt: To be fair to this government, or any government, a lot of the risk aversion was actually from state and territory law enforcement officials. To be fair, while we're all sitting around talking about medicinal cannabis all day, we must remember that the illicit cannabis market is still a major source of diversion of funds by criminal elements, and they had a lot of data about that.

Senator DI NATALE: Sure, but they don't have to comply with any of these regulations, which is why they can make it very, very cheap and why people aren't paying \$1,000 a week to get their medicine.

Dr Skerritt: They have an advantage, yes.

Senator DI NATALE: No, this is actually an important point. This idea that we're so concerned about diversion, the reality is that we've got people accessing the illicit market because they can't get access to product that's affordable and that's accessible. All of the red tape, the lack of investments and the other problems that we've heard about are all what are really driving people to the illicit market. We could reduce people accessing the illicit market if we had a model that worked better, because most people want to know what they're getting; they want to have the assurance that it's appropriate quality, that it's not contaminated, and they'll pay more for that.

Dr Skerritt: When you say 'lack of investment' I'd remind senators that there is almost \$2 billion worth of ASX and private capital in the medicinal cannabis market in Australia.

Senator DI NATALE: I was referring directly to the investment in the Office of Drug Control.

Dr Skerritt: I see. You're not talking about the industry?

Senator DI NATALE: No. The industry are waiting to go. It's not the industry that's the problem here; it's the barriers and obstacles that have been put in its way.

Mr Masri: You've still got to get the balance right in the regulatory framework.

Senator DI NATALE: I agree.

Mr Masri: In the international context, the Australian regulatory framework is well regarded. I think the benefits for industry, especially in the export market, would also be recognised.

Dr Skerritt: I'd remind senators that even if not a single additional licence was granted licence holders with permits, as per our submission, are already authorised to produce over 35,000 kilograms of medicinal cannabis. Again, we can't tell you what companies are making, but we did estimate that about 10 per cent of medicinal cannabis is already Australian made. I believe that by the end of 2020 that might be getting higher; it might be

half, I don't know. But the permits that have been granted authorise 35,000 kilograms, which is an awful lot of medicinal cannabis in Australia.

Senator ASKEW: Can you clarify how many providers there are in that?

Dr Skerritt: The current number of permit holders is—

Mr Masri: There are licence holders and permit holders. At present the number of licences granted, as of last week, that are still in operation is 99, so just short of 100. And the permits that are in operation and are granted are 39. So there is a lag time between the granting of a licence and then production. They might build the facility and so on before they start applying for permits. And amongst that there are a whole lot of applications for variations and so on that add further complexity and further time and further effort.

Senator ASKEW: I just want to get a clarification on a comment that was made earlier this afternoon regarding the need to provide the name and address details for anybody who is actually receiving or having a script done for medicinal cannabis. We were told at the time to ask you, so I'm asking you.

Dr Pegg: Yes, so the application that we receive is de-identified. The details we have of the patient are initials and date of birth, and that's it. That's what's on the approval letter that's issued to the doctor from the Commonwealth. It's that approval letter that needs to be shown to the sponsor, who's the supplier of the product, to enable the supply of that product.

Senator ASKEW: So the actual supplier doesn't receive the details of the person who—

Dr Pegg: Just that de-identified information.

Dr Skerritt: That's from us. We don't even get the names of patients; we just get their initials. What we have been told by some of these medicinal cannabis clinics is that, because they want to build up their own database on efficacy, which we can't under our—the Special Access Scheme is not a clinical trials framework. Some of these clinics say, 'We'll give you 100 bucks off a bottle if we can get feedback from you and your doctor as to how the product has gone.' And that's where full information—they've signed an informed consent between them and the cannabis clinic for it. It's nothing to do with us, and I don't believe it's illegal or anything.

CHAIR: Certainly in my understanding it's separate to what was raised this afternoon where it sounded like it was a requirement.

Dr Skerritt: Certainly not.

Dr Pegg: I wonder if they're potentially also supplying the state and territory approval to enable supply because the state and territory approval, depending on the jurisdiction, may have extra details of the patient. Under the Therapeutic Goods Act that's not required to enact supply; it's the Commonwealth approval.

CHAIR: We need to clarify it.

Dr Skerritt: The states and territories will sometimes need the full name of the patient because, remember, they do check whether the patient has a drug dependency for any schedule 8 drug. We at the TGA don't for our approval.

CHAIR: That's an area that we're going to need to pursue.

Senator URQUHART: I have one final question, which Senator Bilyk wanted me to ask. Have there been any clinical trials of the use of benzodiazepine for the treatment of PTSD?

Dr Skerritt: We can certainly look on the registry of clinical trials and take it on notice.

Senator URQUHART: It would be great if you could.

Dr Skerritt: We would just do an open search on the Australian New Zealand Clinical Trials Registry.

Senator URQUHART: And maybe just a little bit of information if there has been—

Dr Skerritt: This isn't cannabis—

Senator URQUHART: No, it's something different—

Dr Skerritt: this is benzodiazepine for PTSD.

Senator URQUHART: but it came up earlier in the day.

Dr Skerritt: One of our clinicians could quickly check that.

Senator URQUHART: And, if there has been, what the outcomes of those were.

Dr Skerritt: If it is completed, yes.

Senator URQUHART: That would be great, thank you.

CHAIR: We couldn't actually have that form at this moment because it has details—

Dr Skerritt: I've written all over it.

CHAIR: Are you able to provide us with a clean copy?

Dr Skerritt: We'd be delighted to. We can provide you with a de-identified real-world example. This isn't the shortest form; it's a typical form. It does get wearing to hear about 100 pages when you know it's this much. We'll also provide you with a blank form. We can provide you with both.

CHAIR: I've chaired many Senate hearings.

Dr Skerritt: You have.

CHAIR: Many times I've heard doctors talk about the excessive time it takes to fill out forms and things like that, so it didn't surprise me at all when I heard that there was concern about filling out the form. Have you any feedback from people who are using the form about how long it is taking them to do?

Dr Pegg: We haven't studied how long it takes, but I must admit that the feedback we get from prescribers who use the portal is almost universally positive.

CHAIR: When a drug is out of stock and they have to go back—and that was one of the complaints we heard fairly loudly today—does the clinician then need to redo the form? Do they need to go back to the patient? Does the patient need to come back in?

Dr Pegg: I suppose it depends on what discussion has been had with the patient. If the risk profile is perceived by the prescriber as changed, according to the product being different, then they might need to have a discussion. This issue probably is broader than medicinal cannabis. With products supplied under the SAS there is no oversight by the TGA of actual supply, so it's possible that when our approval is received you might go to get the product and it's not there.

CHAIR: Yes, you said that earlier. I understand that that can happen. The process has to be that they come back. There is extra time for the doctor, but does the patient have to come back in for that? Is there another check-up required?

Dr Skerritt: It would vary.

Dr Pegg: There is no requirement from the TGA's point of view that that occur, but I'm thinking in the clinical paradigm that, if I'm a doctor and I hadn't discussed it with my patient—

CHAIR: You might need to. So that's also a barrier for people being able to access this.

Dr Skerritt: This is a common problem. Medicine shortage is one of the biggest threats we have to public health in Australia writ large. They have to go back and substitute another medicine. Because these are on the Special Access Scheme we lack the same powers we have for mandatory reporting of shortages. The Therapeutic Goods Act changed so that as at 1 January last year, 2019, it was mandatory for companies to report shortages only of the registered TGA approved ones, so we don't have good visibility of shortages of these products. It's another reason why we want more of these to be on the register.

CHAIR: We've reached the end of questions today. We've been going a long time today, so I'll call it quits for today if everyone is happy. Thank you very much for your time today. I thank all of our witnesses for their time today and for bearing with us with the sheer volume of what we've heard today. I also thank them for their submissions. I'd also like to thank the secretariat and, very importantly, broadcasting. Thank you very much.

Committee adjourned at 18:25