



HEALTH, COMMUNITIES, DISABILITY SERVICES AND DOMESTIC AND FAMILY VIOLENCE PREVENTION COMMITTEE

Members present:

Ms L Linard MP (Chair)
Mr MF McArdle MP
Mr SE Cramp MP
Mr AD Harper MP
Mr JP Kelly MP
Mrs T Smith MP

Staff present:

Ms D Jeffrey (Research Director)
Ms E Booth (Principal Research Officer)

PUBLIC DEPARTMENTAL BRIEFING—PUBLIC HEALTH (MEDICINAL CANNABIS) BILL 2016

TRANSCRIPT OF PROCEEDINGS

WEDNESDAY, 15 JUNE 2016

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Committee met at 9.30 am

CHAIR: I declare open this public departmental briefing of the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's inquiry into the Public Health (Medicinal Cannabis) Bill 2016. I would like to acknowledge the traditional owners of the land on which we meet and pay my respect to elders past, present and emerging. I am Leanne Linard, the chair of the committee and the member for Nudgee. The other members of the committee are: Mr Mark McArdle, deputy chair and member for Caloundra; Mr Joe Kelly, member for Greenslopes; Mr Sid Cramp, member for Gaven; Mr Aaron Harper, member for Thuringowa; and Mrs Tarnya Smith, member for Mount Ommaney.

Thank you for your attendance here today. We appreciate your assistance with our inquiry. The purpose of this briefing is to receive information from the department about the bill which was referred to the committee on 10 May 2016. I have a few procedural matters before we start. The committee is a statutory committee of the Queensland parliament and as such represents the parliament. It is an all-party committee which takes a nonpartisan approach to inquiries. This briefing is a formal proceeding of the parliament and is subject to the Legislative Assembly's standing rules and orders. You have previously been provided with a copy of the instructions for witnesses so we will take those as read. Hansard will record the proceedings and you will be provided with a copy of the transcript. This briefing will also be broadcast.

I remind committee members that officers are here to provide factual or technical information. They are not here to give opinions about the merits or otherwise of the policy behind the bill or alternative approaches. I welcome our witnesses from the Department of Health.

HARMER, Mr David, Director, Legislative Policy Unit, Department of Health

PERRY, Mr Gregory, Manager, Medicinal Cannabis Team, Prevention Division, Department of Health

YOUNG, Dr Jeannette, Chief Health Officer and Deputy Director-General, Prevention Division, Department of Health

ZGRAJEWSKI, Mr Mark, Manager, Legislative Policy, Strategic Policy and Legislation Branch, Department of Health

CHAIR: I invite you to make an opening statement before we open to the committee for questions.

Dr Young: Thank you very much for this opportunity to brief the committee on the Public Health (Medicinal Cannabis) Bill 2016. I will briefly outline the need for this bill and describe its key features before taking any questions that committee members might have.

I am sure you are all aware there is a growing body of evidence that demonstrates medicinal cannabis products have a range of possible therapeutic benefits and can be used in some cases to treat the symptoms of some health conditions. For example, medicinal cannabis is thought to be beneficial when treating nausea associated with chemotherapy or chronic pain suffered by patients receiving palliative care. However, in many cases the evidence is not clear and more research needs to be done. Queensland and New South Wales are already proposing clinical drug trials to explore whether medicinal cannabis products can be used to treat children with intractable epilepsy.

From media reports and anecdotal evidence, it is clear that some Queenslanders already use unlawfully obtained cannabis products to treat their health conditions. The danger with using these illicit cannabis products is that users have no idea about the concentration of active ingredients or the presence of contaminants, such as pesticides, used during manufacture. As a consequence, they can put themselves at considerable risk. Cannabis is a potentially dangerous drug. When cannabis products are used for medicinal products, they should be used under close medical supervision and in circumstances where doctors and their patients can be certain about the properties of the products used.

The primary purpose of the bill is to establish a regulatory framework for the controlled use of cannabis products for therapeutic purposes that will ensure patients are using medicinal cannabis products safely. The framework proposed in the bill will, if enacted, allow medicinal cannabis products to be lawfully prescribed and dispensed to patients in Queensland while preventing unauthorised use. The bill proposes permitting patients to be supplied and treated with medicinal cannabis in one of two ways.

The patient class prescriber pathway will give certain specialist medical practitioners what is called an as-of-right authority to use medicinal cannabis products to treat particular conditions. Where a patient has a prescribed condition and a specialist medical practitioner has an as-of-right authority to use certain medicinal cannabis products to treat that condition, the specialist will be able to prescribe the medicinal cannabis products to a patient without any other approval from the state. However, as most medicinal cannabis products are not approved therapeutic goods, the treating doctor would still require a separate approval from the Therapeutic Goods Administration, the Commonwealth body, to allow access to the drug for treatment. The regulation in support of the bill will detail the specialists, conditions and products relevant to the patient class prescriber pathway. A national working party will decide the initial list of specialists. Specialty areas are likely to include paediatric neurology, oncology for the treatment of symptoms arising from chemotherapy and palliative care medicine.

The single patient prescriber pathway would apply in all other situations. However, it may also be used for those conditions to which the patient class prescriber applies. The patient's treating medical practitioner—being either a general practitioner or a specialist—must obtain case-by-case approval from the chief executive to prescribe medicinal cannabis treatment for the patient. The approval granted is called a medicinal cannabis approval. An expert advisory panel will be established to advise and assist the chief executive when granting a medicinal cannabis approval. Under the bill all medicinal cannabis to be used in treatment must be dispensed by either a pharmacist who has been granted an approval by the chief executive or works in a hospital pharmacy.

Regardless of which prescriber pathway is chosen, treatment with medicinal cannabis will be subject to certain conditions. These conditions will include a requirement on the treating doctor to monitor the patient's condition and report back on the clinical outcomes of using medicinal cannabis as part of the patient's treatment plan. Another important condition will be of strict prohibition on the patient or their doctor using the prescribed medicinal cannabis product for any purpose other than the patient's treatment. The chief executive is also empowered to grant an approval to facilitate medicinal cannabis products being used in a clinical drug trial. This is called a clinical trial approval, and the expert advisory panel will make recommendations to the chief executive about current or proposed research related to medicinal cannabis.

A draft of the bill was released for broad consultation from 1 March 2016 to 1 April 2016. Members of the public were invited to make a submission by completing a survey on the 'Get involved' website. There were 1,052 people who completed the online survey, and of these over 96 per cent were in favour of treatment with medicinal cannabis. Key health industry stakeholders were also extensively consulted, including medical professionals and representatives from hospital and health services. The bill, and particularly the strict controls around prescribing, dispensing and possessing medicinal cannabis products, was strongly supported by these stakeholders.

The bill makes it an offence to prescribe, possess, supply or administer a medicinal cannabis product unless that regulation activity is authorised under the bill. The possession, supply, production and trafficking of a dangerous drug is also an offence under the Drugs Misuse Act 1986 unless authorised by law. Therefore, persons approved under the bill to use a medicinal cannabis product will also commit an offence under the Drugs Misuse Act 1986 if they use that product contrary to the bill or the conditions of their approval.

The bill does not authorise any person to grow their own cannabis—even if they intend to use it to treat their own health condition—or to use cannabis for any recreational purpose. The bill does not regulate the commercial cultivation or manufacture of medicinal cannabis products. These activities are regulated by the Commonwealth government under the Narcotic Drugs Act 1967.

Prior to today's briefing, the committee requested clarification about the respective responsibilities of the Commonwealth and state governments, consultation feedback and an explanation of the changes to the bill following consultation. This additional information has been included in the written briefing material provided to the committee. I am happy to take any questions.

CHAIR: Thank you, Dr Young, and thank you for your briefing which did go to those questions, and I know the deputy chair also appreciated that because we were unclear about that. I have one very broad question before I hand over to the deputy chair. Cannabis has been around for a long

time. Has it long been used for medicinal purposes elsewhere? What has been the evolution of it? A schedule 8 drug like Oxycontin or Fentanyl patches could equally be misused and are misused and have a significant street value to be used inappropriately. Is it that it is far more understood and has been used in a medical field for much longer? Can you talk about medicinal cannabis generally?

Dr Young: It has been used over many, many decades in some countries in the world. Some countries have quite mature markets in terms of its use. The Netherlands, Israel and Canada have used it for quite some time. The issue is that there have been very few properly scientifically done trials to look at its impact and whether or not it is of benefit. There have been a few trials done. For instance, in children with intractable epilepsy, there has been some work done that has shown that a small cohort of children have responded. In children with a couple of specific conditions—Dravet, Lennox-Gastaut, forms of epilepsy—about a third of them who have failed traditional treatments, both first-line drugs and second-line drugs, have shown some response. We do know that there is some potential there, which is why in Queensland we are starting trials later this year looking at children who have failed current treatments to see if they will have any benefit from using medicinal cannabis products.

Some other trials have been done that have shown that people with end-stage palliation have shown some improvement. In that case, we think it is probably the THC component of the cannabis that is masking and changing their perception of the symptoms they have got rather than treating those symptoms. It is different to epilepsy where it has been the Cannabidiol component that appears to have had the effect. Here it has been the THC component. Similarly, there have been some very limited trials done in other areas but to date the evidence has not been convincing. It has been suggestive but not necessarily convincing, mainly because not many trials have been done.

CHAIR: One of the themes I have read in submissions and heard in comments is this consistent question of why we need to do trials when there has been extensive research and trials done elsewhere and we already know what it does. You are saying we actually do not and to really confirm that medical efficacy we need additional work.

Dr Young: Yes. There have been minimal trials done around the world. The other problem is there are so many different compounds in cannabis. There are not just one or two. There are a couple we know a reasonable amount about, but there are a lot of other compounds so it is quite difficult to differentiate what is the effective path.

CHAIR: Is that different to something like Oxycontin? Is it far more complex because of all those different compounds, whereas there is one?

Dr Young: Yes.

Mr McARDLE: Dr Young, thank you for your submissions both written and verbal. The brief given to us by the secretariat refers to 23 American states having allowed cannabis to be used for medical purposes. Their jurisdictions are similar to ours in many ways—the TGA, the FDA, those sorts of bodies. What work would they have done, do you think, to have satisfied themselves that it could be used across so many different states? I will repeat the question the chair asked of you. I have been asked by people the question of why we cannot simply lift that body of research and place it into Australia, given the regulations, regulatory bodies and regimes are very similar across jurisdictions.

Dr Young: Very sensible. The FDA has approved a couple of compounds as orphan drugs. Epidiolex is one which is a Cannabidiol product produced by GW Pharmaceuticals in the UK. That is a product we are working on at the moment to try and access to use for children here in Queensland. That is an FDA product that has gone through all the rigorous processes that we would go through in this country, so we are very confident about its safety. The issue is whether it is efficacious. We will be doing more work with that.

The other one would be Sativex that they have also approved and we have approved in Australia and is on the Australian Register of Therapeutic Goods. Again, that is a product produced by GW Pharmaceuticals that is particularly useful for some people with multiple sclerosis. That is a half THC, half Cannabidiol product. It is a spray that is used. That has gone through all the regulatory processes via the FDA in the United States and Australia's regulatory processes. There are a few others, but not many.

They are the only products in the United States that have gone through their national process. The national body in the United States has not gone and looked at or authorised any of those products that are being used by those 23 states. Those states have set up their own regulatory processes that

have not been endorsed nationally. For instance, we cannot purchase products from the United States for that reason. When we have imported products recently for one person who has put in an application the product has had to come from Canada. It could not come from the United States.

Mr McARDLE: With the 23 states, are you aware of what research they did before they agreed to release the medicinal cannabis into the public arena? Are we doing the same research here under the terms of the bill as proposed? I am trying to allay the question in the public arena: it has been done elsewhere so many times; what is the problem? Where is the big issue? We need to answer that question, as far as I am concerned. How do we answer that question? There are 23 states in a jurisdiction very similar to ours—a First World Western democracy with very similar regimes on a state level. Why can I not say to John that we cannot adapt that research?

Dr Young: They have done some research in the United States, but it is very limited, looking at various different products. Most of the products that are for sale in the United States in their separate small stores are not being sold through a medicinal process. They are being sold by people who do not have that health background that we are requiring people here to have. We are requiring doctors to be involved to make sure that it is part of the treatment plan for a patient and that it is appropriate and being monitored and it is being dispensed by pharmacists who are approved. That is not the case in most of those states in the United States. It is not in the medical framework.

Mr McARDLE: Your point is that in those states they do not have the rigour of control as to issuance, prescription, monitoring—it is a lesser standard. The research there may be research of a certain level but not what we require to ensure long-term safety of a patient or a child who is five years of age and in 10 or 15 years time, when they hit puberty, things go array because of the use of that drug. We are being stricter and safer. We do not know the long-term impact of the US regime outside the FDA approved one, therefore we cannot adapt that research for safety reasons.

Dr Young: It is for all the reasons that I brought up initially. They are not necessarily produced under good manufacturing processes so you are not sure what is in them, you are not sure of the concentration of the different elements, you are not actually sure what you are giving to people. There is a whole range of issues. Each state is doing it differently. There is not a consistent process.

Mr McARDLE: I will pass over to my colleague, but I want to come back to the point about differentiating between the Commonwealth, the TGA and the bill because it is quite convoluted. I am particularly keen to look at the TGA because they do have a process where you can make an application to them to access certain types of cannabis derivatives.

CHAIR: I think it would be helpful at the end of our time together if you would step us through an example of what that would look like. I think that would assist everyone.

Mr KELLY: Some 23 states are approaching this differently. From speaking to colleagues and contacts in the United States, it would seem to me that in some of those states it is quite possible for an individual to go into a shop where there is no licensed health practitioner, to self-diagnose a problem, to make a selection based on their own aesthetic choices around smell, quality and price with no indication as to what the product has in terms of content let alone therapeutic benefit, to pay whatever the agreed price is and walk out and to administer that product in any way they may choose which could be inhaling it as smoke, cooking it or extracting oil. Is that the case in the United States?

Dr Young: It is the case in a lot of those states. Some of those states have legalised cannabis for recreational use so you do not even need to have a medical condition that might benefit from it, yes. It is variable. Each state is dealing with it differently.

Mr KELLY: I accept that it is variable. Would you say that the approach adopted, without generalising too much, would be a response to democratic pressures rather than a carefully researched and normal therapeutic process that is in place in some of those states?

Dr Young: It is very different to the process that we are advising should occur here in Queensland.

Mr KELLY: In your submission you say there is a growing body of evidence about the therapeutic potential and that there might be some possible benefits?

Dr Young: Yes.

Mr KELLY: We have a growing body of evidence that something might be possible. That is a very far cry from saying there is conclusive evidence that the four conditions listed would definitely be helped by the addition of these products to our array of therapeutic goods; is that correct?

Dr Young: I believe there is enough evidence that we need to work through that and see where there is benefit. I do not think we should ignore that growing body of evidence, but we need to take it on board and work out what will be useful and for whom it will be useful.

Mr KELLY: Are there any other medications used for those four listed conditions or any other conditions where we do not have conclusive evidence and we may not know the side effects of those products but we go ahead and use those products anyway?

Dr Young: We are always involved in clinical trials with a whole range of new products and they are very tightly managed and controlled, of course. Yes, we do use products before we know their full likely impact because we are forever trailing new things. There are always new things available. Yes, there are.

Mr KELLY: Certainly in the area of oncology care I imagine there would be a lot of cases where we are trialling new products and doing something fairly similar to what we are doing here?

Dr Young: Yes.

Mr KELLY: Your submission notes that the use of this medical cannabis is going to be permitted under strict medical supervision and integrated into a patient's treatment plan. How is that different to any other medication that we would administer in this state or this country?

Dr Young: We are going to ask for information back because we want to start understanding who is likely to benefit from this and which products. We really want to get more information. The only way we will be able to get that is to ask the people who are using it to give us information.

Mr KELLY: Sure. I note there is a whole range of forms it will take. Based on what you have said already, these forms will be delivering a measured and accurate dose, similar to the way other medications deliver doses?

Dr Young: Yes.

Mr KELLY: Given the experience overseas, is it clear that there will be no form of the product available that will be inhaled in smoke form into the lungs?

Dr Young: It is extremely unlikely. I am reluctant to say never, because you never know what might come out. If there is evidence and it is the right thing to do then there is the ability to do it. I think it is highly unlikely. I am struggling to think when it might be useful. There is always likely to be something that might eventuate. At this point in time, I think it is very unlikely that we would recommend that anyone smoke the product.

Mr KELLY: A good scientist never says absolutely never. If the bill passes, would the products be listed on the PBS?

Dr Young: They would have to go through the usual processes—efficacy and then cost efficacy. Before they would get onto the PBS, if they do, they would have to go through and get onto the Australian Register of Therapeutic Goods. That would mean that they would have to show they are efficacious and safe.

Mr KELLY: Would the current level of evidence satisfy that criteria, do you think?

Dr Young: Sativex is already on the Australian Register of Therapeutic Goods. It did not get onto the PBS because it did not meet those cost-effective requirements. I suspect that Epidiolex might get onto Australian Register of Therapeutic Goods, but that work has not happened yet. There are products that, yes, I think could get onto the Australian Register of Therapeutic Goods. They will have to be reproduced in a reproducible manner and people will have to know exactly what is in them. As to whether they get onto PBS, we will have to wait and see if they meet those requirements.

Mr KELLY: For the products that are going to be used for children with untreatable forms of epilepsy, what is the likely cost to the user of those products, or are they simply going to be supplied as part of an ongoing clinical trial?

Dr Young: Initially they will be part of a clinical trial so they will be free to those children and their families. If they were to get on to the Australian Register of Therapeutic Goods then that trial would of course end. As to the cost of them, we do not know at this point because they have not been put on the market. GW Pharmaceuticals is not selling them at the moment. They are only providing them under compassionate access programs for free. Sativex might give an idea; I do not know. It is a completely different drug for a completely different purpose. At the moment it is around \$20,000 per year per patient, depending on the dose. For some people it can cost a lot more than that because they need much higher doses.

Mr KELLY: Hopefully if the clinical trials go well it will satisfy that and the cost to the end user is then handled the way we handle any other medication?

Dr Young: It would depend whether it gets onto the PBS—whether it meets the cost-effective process the PBS goes through.

Mrs SMITH: One of the concerns I have is with regard to the limited trials that have been done. We are especially talking about kids. I am concerned about the long-term effects, especially if we are treating three-, four- and five-year-olds. What is the long-term effect going to look like?

Dr Young: It is definitely a concern. Doing anything with children is always a concern. Here we are not that concerned because the product we are planning to use, Epidiolex, does not contain any THC. That is the component that really causes that long-term risk of potentially developing psychosis. It is Cannabidiol which has gone through multiple animal models.

It has also gone through phase 1, 2 and 3 trials in the United States. It has not gone through the final trials in terms of being able to get onto the Australian Register of Therapeutic Goods or the PBS trial data. It has really gone through all of the safety trials. Whether it works still has to be fully determined. There is some strong suggestion it does for a very small group, but we are quite convinced it is safe. We are comfortable with that.

Mrs SMITH: You talked earlier about oncology and palliative care. We have talked about kids. What other illness would be treated in the trials? How broad will the scope be?

Dr Young: At the moment that is the trial we are focusing on because of the evidence that is available and because some of those children really have no alternatives. They have failed first-line therapy. They have failed second-line therapy. Often they have been put on five or six different drugs with some very difficult side effects. Really, this is to try to see if something will work for them. That is the group we are focusing on at the moment. As we go through and products become more available we will look at other areas that might be of benefit—those ones I have discussed such as palliative care, chemotherapy induced nausea, adults with epilepsy. They are the ones that we think might have some benefits from the drugs.

Mrs SMITH: You have talked about specialist pathways and then the single class having to be approved on a case-by-case basis by the chief executive officer. Is that at each of the 17 health boards or is it just at one single desk? Would that end up being practical? Do we have any idea of what numbers we would be looking at in using this as treatment?

Dr Young: At this point in time, we have had one application.

Mrs SMITH: The floodgates are not open. You are not just sitting at your desk all day signing off?

Dr Young: At the moment the chief executive, by definition, is the director-general of Queensland Health, but he can delegate that responsibility down. If we were flooded, we would have a team working on that, but at this time we certainly have not been.

Mrs SMITH: We have talked about, at this stage, we have had one application.

Dr Young: That is under the regulation that was amended late last year to enable prescription in Queensland. It was done under that regulation.

Mrs SMITH: We have talked about all the places that have implemented it. Are you aware of any states or countries that have looked at it and then chosen not to go ahead with it? Do you know the reasons?

Dr Young: Some countries are starting to pull back a little bit. They have found that it has got out too broadly and it is not being used only in that medical, therapeutic—

Mrs SMITH: That is my biggest concern.

Dr Young: Yes. They are starting to tighten it up, whereas Australia has chosen—both at the Commonwealth and here in Queensland if this bill were going to go through—to have it very tight initially and then the plan is to review in two years and see where we stand. There will be more evidence available then about therapeutic benefits. We will know then how many people are interested in pursuing this. We will be able to look at whether the model that we are suggesting here today is the right one to go forward into the future. We are very tightly controlling this in this country within a medical framework.

Mrs SMITH: Are you aware of any countries that have had the opportunity and then chosen not to go ahead?

Dr Young: I do not think not to go ahead; I think more that they have gone ahead in a very liberal way and are starting to pull it back. For instance, Italy decided to go with only one grower in the end and to pull it right back—instead of having multiple sources to have only the one source. Israel has been looking at tightening some of their processes. Canada put out an expressions of interest licensing program and had 1,400 applicants—people who wanted to grow cannabis for medicinal use. They gave 29, I think it was in the end—

Mr Perry: Twenty-four.

Dr Young: Twenty-four and they think that is too many, so they are looking at what they can do there. Yes, it is a very fluid space, if I can put it like that, around the world. There are a lot of people looking at how they have done this and how they have managed it and how they need to manage it into the future.

Mr HARPER: I am interested in the trial. I have been dealing with eight constituents who I have treated over the years for multiple seizures and who are very keen to get on a trial. When will it start? Will it just be the paediatric cohort or will this go to oncology for pain relief? How do people get on it?

Dr Young: At this point in time, the plan is to do a trial later this year for children through the Lady Cilento hospital. Anyone who wants to get involved in that should go to their current treating physician, or general practitioner, and ask to be referred, if they are not already—they probably are, but if they are not already—to one of the paediatric neurologists at the Lady Cilento. That is the best way.

Mr HARPER: And the million dollar question—I am sure you will have a lot of people also happy to grow in Queensland. Where is it expected that it will be grown in Queensland?

Dr Young: That is totally up to the Commonwealth. This is Commonwealth legislation. I have been going out around the state speaking to farmers to make sure they are aware of the different legislation that is potentially going to be in place at the Commonwealth and at a state level so they understand how they can progress if they wish to get involved in growing cannabis for medicinal purposes.

Mr HARPER: Going back to pharmacology, when we deal with pain management I think they go to the opiate receptors, mu, kappa. Do you know how it works in that oncology setting for pain relief? You said THC. Can you break it down a little bit so that we can get an understanding?

Dr Young: It is thought that THC masks the perception of pain. Rather than treating the cause, or treating the pain itself, it changes the person's perception of it.

Mr HARPER: Okay. There have been some good—

Dr Young: I do not know about 'good'. There have been some trials. As I say, this is an evolving area of expertise.

Mr HARPER: Are you looking to extend that trial from paediatric into that—

Dr Young: We will start with paediatric and the idea is that an expert advisory committee, as part of this bill, will be put in place—if the bill is passed—and then that committee would advise the director-general, or chief executive of Health, about trials that we should be considering and working through.

Mr CRAMP: Thank you very much for coming today, Doctor. I have a question following on from the question asked by the member for Thuringowa about the economics of it all. The committee understands that the New South Wales government has applied for a licence to grow medicinal cannabis. We see that in Tasmania they supply about 50 per cent of the world's licit opium product. I think you touched on it, but I just want to clarify this: is Queensland Health going to support the possibility of having our farming industry apply for licences to grow medicinal cannabis? Can we see an economic benefit for the state as well, because I understand from what you have been saying that currently we are importing it from Canada? Is that something that Queensland Health is going to be supportive of, or do you not have a position on that?

Dr Young: Yes. The Queensland government, I understand, is fully supportive, but it is totally up to the Commonwealth as to how they are going to put it in place. Of course, they are in caretaker mode at the moment, so we have not been able to clarify with them what their thinking is. They have made a few comments that we have tried to unravel and work through, but we really need to wait and see the regulations that come out of the bill. The bill has been passed through both houses of parliament, but the regulations have not been drafted and made public at this stage.

Mr CRAMP: I note that you are starting with paediatrics around epilepsy. You said that in around two years you would look at reviewing it to see if you are going to widen it. I am interested in people dealing with chronic pain, oncology and CA patients. It is my understanding that they are possibly going to have to wait for two years before we look at that—or is that just based on the paediatric epilepsy cases that we are looking at a two-year period?

Dr Young: No, the two years is to review the bill. If it gets up, the recommendation is that in two years, given that this is such an evolving area, we need to then look at whether it is meeting the purposes for which it was put in place. We have started now, initially, with those trials aimed at children with intractable epilepsy, but then we will work through whether there are other areas that we need to start doing research and clinical trials in. That will not wait for two years.

Mr CRAMP: Let us cross that bridge and say that the bill is passed. You will then start reviewing issues like chronic pain management and CA patients and work through that?

Dr Young: Yes.

CHAIR: Could you please step us through the practical process that both the prescriber and a patient would go through, as proposed by the bill, to access medicinal cannabis?

Dr Young: Yes. There are two pathways. When we have some ideas, some evidence and some discussion at the national level—the idea is to try to harmonise this around Australia—there will be certain groups of specialists who have done some specific training and who will be authorised as-of-right to prescribe.

CHAIR: Would that, for example, be a palliative care specialist?

Dr Young: Yes.

CHAIR: Is that what we are talking about?

Dr Young: Palliative care. At this point in time we think it likely, but it has not been firmly decided—this is all just potential—that it would be palliative care; it would be oncologists for the use of chemotherapy induced nausea, not for the treatment of cancer, because there is no evidence at this stage for that; and paediatric neurologists. Those are the three who we think would initially potentially be made able to prescribe as of their positions. They could do that. A patient who is under the care of one of those three would have that discussion with their doctor, that they think medicinal cannabis would be of benefit. They would work that through. Then that doctor would be able to prescribe it without coming to the state for approval. They have already received that approval, because they have the appropriate skills, training and knowledge and it is for a condition that has been agreed could benefit.

They would have to report on the outcomes, because we want to know how people respond to the different products. If that product was not on the Australian Register of Therapeutic Goods, they would still have to go to the TGA for approvals.

CHAIR: 'They' being—

Dr Young: The doctor. The doctor would have to go to seek approval.

CHAIR: What does that look like? They apply via a letter? How long do they wait? What does that look like for the patient?

Dr Young: I am sure that it will get faster as the TGA starts getting these sorts of applications. They have had very few to date. They have only had one that has involved a THC substance, which is the one out of Queensland. Out of the whole of Australia they have had one THC. They have had a few other applications that have involved Cannabidiol products, but not a lot.

CHAIR: Have they approved them all?

Dr Young: We know that they approved ours. We do not know about the other states. I understand they have, but it is not public information.

CHAIR: If they come back and say yes, then what does the doctor do? Where do they get that product?

Dr Young: Then we will have approved pharmacists in private community pharmacies throughout the state. They have to apply for approval. They will have an approval so they can go and get it from one of those approved pharmacists, or they could go to a hospital pharmacy—a pharmacy in a public hospital which, under the act, if that is approved, would be able to dispense.

CHAIR: They may likely have to get that in. It would not be something that they would have readily.

Dr Young: They would have to import any such product from overseas, because there is no medicinal cannabis grown in Australia at this point in time. Eventually, once people apply for licences under the Commonwealth legislation, there will be products that will be able to be grown in Australia and they will be able to access those products.

CHAIR: How long might that take for that patient, if they had to bring the product in and go through the TGA? Do you have an example of a time period?

Dr Young: I can only give you the one that we have had to date, but it was the first. It took a year for the TGA to approve that, then it took a month for us to approve that and now the family is importing the product from Canada. I do not know how long it would take them to organise that importation.

CHAIR: Okay. We would expect that to get a lot faster?

Dr Young: I would think so. The first time you do anything is always going to take much longer—and that product had a high count of THC in it. It needed to go through all sorts of processes to be looked at by the Commonwealth and the state.

Mrs SMITH: How does that then work with Customs and getting it through?

Dr Young: TGA gives an import licence so that Customs are notified, yes. That is really streamlined. That has not—

Mrs SMITH: How would that work, then, if people are using this and then taking it overseas to Bali or Thailand or something like that?

Dr Young: People must always obey the laws of the country they are going into. They would need to look at those laws.

Mr McARDLE: Being very simplistic, the Commonwealth legislation allows a licence to issue to grow the plant.

Dr Young: Yes.

Mr McARDLE: The TGA issues the approval to use the drug in Australia.

Dr Young: Yes.

Mr McARDLE: The bill allows the use of drugs being approved by the TGA—either on the register or applied to the TGA to use a particular type of drug. Without that approval, the drug cannot be used by the patient legally in this state. Is that how it works?

Dr Young: Yes.

Mr McARDLE: Fine.

Dr Young: I have a beautiful—

Mr McARDLE: You have a flow chart. Lovely. Do not confuse me again.

Dr Young: No. It has been done by the experts.

Mr McARDLE: I want to ask you one question, however. The bill, as I read it, does not provide an indemnity for doctors who seek the approval of the chief executive to supply a drug to a patient; that is correct, is it not? There is no indemnity there, as there would not be in any circumstance anyway; is that right?

Dr Young: From memory there was something I read somewhere—

Mr McARDLE: The reason I ask is that we are going here into uncharted waters in this state; therefore, a health professional, whether it be a doctor or a nurse, as the case may be, would make a telephone call to their indemnity company.

Dr Young: There are clauses 193(3), 194(2) and 195(2). They were new provisions inserted to replace the existing protection from liability for state employees. Chapter 1, part 3 of the Public Service Act 2008 provides broad standardised protection from civil liability for all state employees, and the new provisions reference relevant sections of the act rather than replicate this protection in the bill. The bill points people to the indemnity that is currently in place.

Mr McARDLE: That would be a public servant, but if I am a GP at Geelong or Caloundra and Mrs Jones walks in, I am not indemnified pursuant to this bill, am I? If I am prescribing a medication, even though it is approved by the health department, the onus falls back on me as a medical practitioner to ensure my indemnity insurance covers me. It might well be that because the drug is on a trial basis there are issues around the insurance coming on board immediately without being satisfied that the risk is low or non-existent. Would that be a realistic position?

Dr Young: In terms of trials there are different processes, and at this point in time I imagine the trials are going to be done in the public system so you will not find a GP out there or a specialist out there in their private capacity getting involved in trials. In terms of them prescribing a drug—

Mr McARDLE: Single patient prescriber for that one.

Dr Young: Yes, if they are prescribing then that is no different to any drug that they are prescribing. For any drug they must have a discussion with the patient before they start them on that drug and say what the issues are. That is true whether that is an antihypertensive, a cancer drug or anything. They have to have informed consent and the patient understands what they are taking. We are putting in place training for doctors who wish to prescribe medicinal cannabis so that they understand the limitations behind it, what evidence is actually available and what the potential harms are.

Mr McARDLE: I as a doctor would run straightaway to my insurance company to say, 'I have been given this. Am I covered?' If I do not I am a fool, put it that way.

Dr Young: Yes.

Mr McARDLE: I understand that the Lady Cilento trials you spoke of are not currently in place, but preliminary steps are being taken now at the Lady Cilento with regard to identifying potential children, shall we say. Will that trial not start until the expert panel is formed, if the bill is passed?

Dr Young: No, we already have an expert panel in place that has been involved.

Mr McARDLE: Which legislation was that set up under?

Dr Young: That was not set up under legislation. That was a request from the director-general.

Mr McARDLE: What gives it its authority as an expert panel at law to assess and trial and undertake research et cetera?

Dr Young: It is no different to any other panel that is set up to run a trial. We run many, many clinical trials in Queensland Health every day for a whole range of conditions, and we utilise experts in that area to put together the trial protocols and to work through them. It is no different to normal business.

Mr McARDLE: The New South Wales model has an end-of-life use. I am a bit confused, as I always am with New South Wales. Is it medicinal cannabis or cannabis they allow?

Dr Young: Cannabis.

Mr McARDLE: It is cannabis, per se?

Dr Young: Yes.

Mr McARDLE: THC is involved in that process?

Dr Young: They have no idea what those people actually consume. It is people who have obtained cannabis from the illegal market and are taking it at end of life for their benefit. New South Wales has introduced a process so that the police can use discretion whether or not to prosecute someone who is on a register as taking this cannabis.

Mr McARDLE: Which they can now anyway. The police have discretion in any event, whether it be Queensland or New South Wales, to charge or not to charge. It is formalising an existing arrangement.

CHAIR: Dr Young, you were talking about the two pathways and you went through the patient class prescriber. Can you talk about how the single patient prescriber differs and what that looks like?

Dr Young: It means that any doctor—

CHAIR: Like a GP?

Dr Young: Yes. A GP or a specialist—any doctor—can prescribe medicinal cannabis for any patient for any condition. Then that will go to the expert panel for them to look at whether this is a reasonable thing to do or not. There are two issues there. First, you have a doctor who needs to be looked at in terms of their knowledge and skills, whether they have the right expertise to prescribe cannabis. Secondly, the expert panel would need to look at whether the condition that it was being prescribed for was a reasonable condition for cannabis to be used. The expert panel would then make that decision and make that recommendation to the chief executive, the director-general of Queensland Health, who would then approve it or not approve it. At the same time, that doctor would need to apply to the TGA as the other pathway. It is just a different way to allow; otherwise, it means that we would not have any ability to allow people outside those initial areas that we were considering or those initial groups of specialists to prescribe medicinal cannabis for their patients.

Mr KELLY: Dr Young, I am just intrigued by the New South Wales situation. Police determine whether or not a person is on a palliative pathway and able to utilise cannabis; is that correct?

Dr Young: No, those people need to be on a register. They need to seek from the health department, I think it is—

Mr Perry: Justice.

Dr Young: From Justice, sorry.

Mr Harmer: It is the Terminal Illness Cannabis Scheme in New South Wales. Patients who have a terminal illness can register under the TIC scheme, and then police are aware of who is registered and make the determinations about prosecuting or not.

Mr KELLY: Thank you for that. That clarifies that. I wanted to ask you about education if the bill is successful and passes. I have a relative recently diagnosed with cancer and I have already had contact from people saying, 'We will get you some marijuana because it is going to be legal soon anyway.' There is a great deal of misunderstanding in the community as to what we are actually proposing and doing here, particularly from all groups of patients and people who are seeking assistance in this way. What education is the department proposing to undertake to ensure the community understands exactly what is being proposed and implemented?

Dr Young: At this point in time we are going out across the state and doing workshops with farmers and other interested people in various communities, so we have had reasonable attendance at that. Once the bill is passed, if it is passed, of course we will be doing education then and getting that information out to people. We have engaged with the various stakeholder groups such as the Queensland branch of Epilepsy Australia. We have been working with various groups and keeping them informed of where things are up to.

Mr KELLY: The trial for, say, the unresponsive epilepsy conditions is a trial for a condition where currently the existing treatments are failing. For the conditions where it is for pain and nausea relief we currently have a range of other options for pain and nausea relief; is that correct?

Dr Young: Yes.

Mr KELLY: If Queensland Health chooses, based on the advice from expert panels, to pursue the development of additional therapeutic goods for the relief of pain and nausea, will that create a situation where we are drawing resources away from other areas of research into conditions or situations where we have no active treatments at the present time?

Dr Young: Not all people who have chemotherapy induced nausea get adequate relief from that with current treatments, so it is really no different to the children with intractable epilepsy. It is designed as an additional therapy for a small group of people. I think as we look more into the human genome we are going to find that with a lot of these conditions people with different genetic profiles respond differently and we will start finding that there are subgroups that respond to different things.

Mr KELLY: In my experience, pain and nausea are quite subjective conditions. I have given significant amounts of pain and nausea medication to person A—and I am only going on a small anecdotal group of patients—that in my experience I would expect to stop anyone's pain, and that person continues to report pain; whereas person B gets almost nothing and says, 'I'm fine,' and gets out of bed with a condition that should be completely excruciating. I guess what I am trying to explore here is: what is the opportunity cost of developing another pain and nausea medication that this will present?

Dr Young: I do not know what that cost is. At this point in time the Queensland government has put aside \$3 million towards trials over the next three years. Whether that increases I do not know, but I think it is a reasonable thing to do. When there is this emerging body of evidence suggesting that things are useful, we explore that for the benefit of patients in Queensland.

Mr McARDLE: I refer to the Lady Cilento trials that are commencing later this year. Are they over a three-year time line or a two-year time line?

Dr Young: No, the trial will be until the drug is assessed as being appropriate to be on the Australian Register of Therapeutic Goods. Once it is available through that then we will be able to purchase it as with any other drug, so you would not continue the trial beyond that point.

Mr McARDLE: There is no time line to reach that point? There is no assessment process in place by way of an expert panel or the peer review body?

Dr Young: No, we will work through. Those children who do not respond will of course be taken off it; there is no point in them continuing. For those children who do respond, we will keep them on it once we have started them on it. It is a compassionate access trial rather than being an efficacy

trial. We will feed the information into the world literature, of course, and it will provide more information. We want to get it for Queensland kids that will benefit, and if they benefit we will keep them on that therapy. We do not intend to remove it from them; that would be pointless.

CHAIR: The time for questions has expired. Thank you all very much for your assistance here today. I declare the briefing closed.

Committee adjourned at 10.27 am