

AJP PODCAST: MANAGING MEDICINAL CANNABIS RISK

PDL professional officer Kylie Neville discusses the issues pharmacists face when it comes to medicinal cannabis, with our podcast.

Speaker 1 (00:01):

Welcome to the AJP podcast, a podcast for pharmacists by pharmacists where we discuss current events, relevant topics, and emerging issues. I'm your host, Carlene McMaugh, and together with the AJP I'm bringing you the opinions and expertise of different pharmacists to discuss their views and insights on topics relevant to pharmacists. Please like and rate each episode and subscribe to the podcast so you don't miss an episode.

Speaker 2 (00:26):

So the first thing I'm going to ask is can I please ask you to do an introduction for yourself?

Speaker 3 (<u>00:32</u>):

Yes, absolutely. Who

Speaker 2 (<u>00:32</u>):

Are you for the audience?

Speaker 3 (<u>00:34</u>):

Yeah, absolutely. So my name is Kylie Neville. I work for PDL, which is Pharmaceutical Defense Limited, and I've been with them only roughly coming up to three months. I'm a relatively new professional officer. I'm one of five professional officers with PDL. My background is predominantly in community pharmacy that I have also touched into hospital pharmacy as well, both private and also public hospitals. So definitely a great situation to be here at PDL because I'm able to use my decades of experience to help with pharmacists who might be in a situation of high risk or vulnerability, and they might be undergoing a regulatory matter that requires assistance from PDL. So yeah, that's the short and sweet of my background.

Speaker 2 (01:34):

Thank you. Can I please ask you what are some of the risks involved when pharmacists dispense medicinal cannabis?

Speaker 3 (01:41):

Absolutely, yes. So there are a few different risk areas. The great majority of medicinal cannabis products prescribed in Australia today actually fall under the category of being unapproved products, which means they don't appear on the ARTG, which is the Australian Register of Therapeutic Goods. So this means that you can't simply just go to a doctor, request a script and have it filled at the pharmacy as you would with an ARTG registered medicine. So these unapproved products still actually need to meet standards which aim to make sure the products have reliable cannabinoid content and are actually free of contaminants. So that's the first sort of thing to think about. So if we go right back to the starting



ground and the first moment when we see or take in a script from the pharmacy at the counter, so there's times when the pharmacist doesn't know who the prescriber is and if that prescriber might be using, say the T-G-A-S-A-S pathway, which is one way for a prescriber to have approved product approval, pardon me, for their patient to obtain medicinal cannabis, or some prescribers have done a little bit more in terms of what they're able to do and they become what we call an approved prescriber.

(03:06):

So pharmacists don't always know this about a prescriber. There's no sort of telltale on whether or not a prescriber is an approved prescriber or they might be using the SAS pathway. So firstly, having access to the correct paperwork that companies a medicinal cannabis script such as the copy of the TGA approval, they say S approval is critical because that should be handed over to the pharmacist as they'll need that when they're dispensing the script to legally dispense the script. So that's probably my first point to think about is right from the beginning is when we're taking in that script, sometimes you also need that paperwork that TGA approval paperwork might be required when you're ordering a script from a supplier or a wholesaler, sorry, ordering a product from the wholesaler. Another risk area is when pharmacists encounter prescriptions that have been written for a category of medicinal cannabis products using a range of THC percentages instead of an exact percentage.

(04:13):

So for example, a script might be written for, say a dried flower in a range of 18 to 22%, for example. So this is problematic because a prescription for medicinal cannabis really needs to specify a precise strength to be valid. Adding onto this point, actually substitution for another product cannot occur even if the doctor has verbally told you to do that or even written it, it's actually not valid. So a new prescription is required if a different product is dispensed for a patient. So that's another sort of critical aspect there that we look at with risk. A further risk can occur when conveying dosing information to the patient. So for example, a patient's been told by their doctor to use a maximum one gram of dried flower daily as needed. So the patient may not have any knowledge of how much one gram is. This is a really different dose form to what pharmacists are more familiar with.

(05:21):

So most pharmacists know that a tablet contains X amount X milligrams of medication. So medicinal cannabis often involves a variable dosing when a patient might be using cannabis to treat a condition like maybe even, I'll just give an example of migraine, which can change in intensity, their symptoms change depending on the day or other lifestyle factors that come into the way they're dosing. And another risk, I thought of another one to talk about is there are times when a patient has received advice from their prescriber to dose with two or more, and sometimes we see quite commonly patients with six to eight or sometimes higher prescriptions for medicinal cannabis products. So as pharmacists, we're naturally wary of anything that is a schedule eight medicine, and we often feel overwhelmed in not knowing the exact way a patient will use their medications. So the therapeutic use of medicinal cannabis is not black and white and actually takes in shades of grey. So yeah, those are sort of my little summaries there of the main risk. Yeah,

Speaker 2 (<u>06:38</u>):

Thank you. What types of issues should a pharmacist be aware of when handling, storing and dispensing medicinal cannabis?



Speaker 3 (06:48):

Absolutely. That's a great question. Pharmacists always would want to keep in their mind that a large many of medicinal cannabis products are schedule eight and they should be treated as such. So it's wise for pharmacists to review the use of the medicinal cannabis with a patient as you would with any other medicine and counsel on the safe and appropriate use. If there are repeats on a medicinal cannabis script, those intervals should be adhere to. And although toxicity risk below when it comes to medicinal cannabis in comparison to say an opioid, there can still be many situations when the overuse of cannabis can lead to harm. Another thing is we want to remind patients about DHC and driving laws. That's essential. So that's an issue that a pharmacist should have in the back of their mind when they're speaking with a patient just to have that in their counseling aspects. I think pharmacists might see medicinal cannabis in a different light to say regular medications that we're familiar with. And this is a bit problematic because as with any Schedule eight medicine, if you are unsure who the prescriber is, it can pose a risk situation. Looking up a prescriber on Ahpra can often give you information like a starting point if it's somebody that you don't know who that prescriber is.

(08:22):

So that's probably more talking about the issues to be aware of when it comes to dispensing. Thinking about your patient's history and in regard to where medicinal cannabis may fit in, sometimes you might have a full medication history of a patient, sometimes you are meeting that patient for the very first time. As with any other medicine that you'd be dispensing for the first time, there's a great benefit in knowing and understanding the therapeutic needs of that patient. So using say real time prescription monitoring can give valuable history to allow pharmacists to conduct a risk assessment for the patient before they use that and ongoing throughout their time when they're using that product as well. When it comes to storage of medicinal cannabis, which is another area where we have seen regulatory actions towards pharmacists, it's so important to remember medicinal cannabis products, which are Schedule eight, do require storage in a lock safe that meets those schedule eight requirements as per your state and territory legislation. If a medicine that's kept in the fridge such as an example would be like nabiximols, which is like the brand name Sativex, it's to be stored in a locked fridge that secured to the premises in the same way that say, a Schedule eight safe would need to be secured to the premises. So those are the sorts of issues. Just a brief little rundown on what to think about when you're handling and storing medicinal cannabis. And yeah, I hope that answers that question.

Speaker 2 (<u>10:07</u>):

Thank you. Can you also discuss for us the types of incidents that you're seeing being reported to PDL relating to medicinal cannabis?

Speaker 3 (10:16):

Absolutely, Carlene. So this is something that we're all passionate about at PDL because we don't want anyone to be reported or have any regulatory notification regarding this. So some of the things that we see most commonly is that pharmacists might feel tempted to substitute a product without authorization. So for example, if a script has been written for a cannabis flower, I'll give an example, which is say 20% and it's particular strain. It's a particular one that the doctor has prescribed, and that's what the doctor would like the patient to have, and you don't have it in stock and there's problems getting it in a timely fashion. The patient might, the patient may be giving you some pressure. I'm sure



pharmacists listening to this will know how that feels to have someone applying some pressure to have it dispensed as soon as possible and to have it available.

(11:16):

It's something that we see, and I want to emphasize that it is essential that pharmacists stick to what is prescribed. Interestingly, even providing a lower percentage, so just say you had a 19% flower in stock and it doesn't meet, of course, the 20% what was written on the prescription that has actually caused issues providing a lower strength. It'd be the same as imagine if you had Oxycontin 15 milligrams in the safe and the doctor had prescribed 20 and you just didn't have the 20 in stock and it out of stock or hard to get. We absolutely as pharmacists wouldn't ever just give a lower strength hoping that it would be fine. So even though there is a minimal difference between those percentages of say a 20 and a 19%, it still doesn't adhere to what the prescriber has asked to do. The other incidents that we see are storage conditions keeping medicinal cannabis products out of the safe or not securely locked has definitely resulted in pharmacy owners receiving complaints.

(12:26):

Inspections can be random, so it's important to follow Schedule eight guidelines for storage. Definitely patients can often have unreal expectations around the supply of medicinal, medicinal cannabis products in a pharmacy, and it often takes longer than to order in than say, a straightforward order through a major wholesaler. I think it's important to highlight to many patients right at the very start that if there's a product prescribed, if they've had a product prescribed that might take some time to order in or whatever reason it's out of stock, that there will be delays. I think pharmacists by our willingness or wantingness to help people are often in a hurry to please so much that it can cause a misunderstanding of the time constraints and there is extra paperwork that's sometimes needed when ordering. So we will have complaints made against pharmacists from patients who are frustrated by the process.

(13:33):

Another area where pharmacists are receiving complaints is when a patient exceeds their specified limits. So if a doctor's script has stated that they might be receiving X number of grams or they shouldn't exceed X number of grams per week or so, patients might push the pharmacist to supply sooner than the script is specified. So in the case of a Schedule eight medication, it's so important to follow those guidelines just with any other Schedule eight medicine. If a patient presented early, we would probably decline or at least speak out more information such as contacting the prescriber details or ask for advice. And probably the last other big thing that when I talk about incidents, another one that I look back and had a look at the historical information was the differences in state laws can present a challenge. In some instance though, for example, with our migratory workforce living and working in different states, for example, if you are say, a Queensland resident and you're traveling to New South Wales to live or work a New South Wales pharmacist can dispense a script from another date as long as the prescriber is Ahpra registered and the pharmacist has evidence that the doctor has approval from the TGA to prescribe.

(15:06):

Interestingly, if you were to travel to Western Australia, only WA-based medical practitioners can write a script for medicinal cannabis, and the script can only be dispensed at a western Australian pharmacy. So those are the sorts of major incidents that we sort of see as just being caught out by maybe differences in state laws or that's something that, and it's really hard to be across every state law and



every piece of legislation, unless you are working in that state, you often don't. Some pharmacists wouldn't really, unless you maybe on a border town, if you're working in a border town, you might know those things, but most pharmacists won't know the legislation in other states, and people do move around and they work in different areas. So yeah. So those are some key aspects or key incidents that we see here at PDL.

Speaker 2 (16:02):

Thank you. What can pharmacists do to reduce risks when dispensing medicinal cannabis?

Speaker 3 (16:09):

Yeah, absolutely. Good question. So real time prescription monitoring is a way to gain insight into the frequency of a patient who's receiving, say, a medicinal cannabis product. If it's a Schedule eight product, of course schedule four products like CBD oils, we wouldn't really necessarily see those pop up at all on any sort of monitoring program. So in the case of a patient having multiple prescriptions going at the same time, which does happen, it helps if the pharmacist can calculate daily dose, total use, sorry, the total daily use or weekly total grams, which can be stated by the prescriber. So it's sometimes it's complex to work out if somebody is getting close to their limit of stated what the doctor has stated on the script. Also, real-time prescription monitoring allows you to see if the patient actually has multiple prescribers for medicinal cannabis, which can occur.

(17:17):

So all medicinal cannabis products do require vigilance, and if you are dispensing schedule eight medication, it's great to follow. It's so important to follow those dispensing and storage requirements, and that goes a long way to reduce the risks that pharmacists face when they do handle medicinal cannabis products. Also, make sure, ensure you have good record keeping habit in your pharmacy store, your paperwork in a way that makes it easy to find should you need to find those records quickly. For example, if you were in an audit process, you'd want to be able to have those on hand pretty easily or in a safely filed database. So be aware that medicinal product cannabis products are highly sought after on the markets and are often at risk of being diverted. So keeping vigilant is everything when it comes to reducing risk, when dispensing medicinal cannabis products. Yes,

Speaker 2 (18:26):

And many pharmacists have not undertaken training in medicinal cannabis products, and as such often feel out of their depth when it comes to patient counseling. So what can be the reason for this and maybe some ideas on how patients can, pharmacists can better counsel their patients?

Speaker 3 (<u>18:44</u>):

Yeah, absolutely. This is a really pertinent point, so it's interesting. So there's really only two products, medicinal cannabis products on the ARTG that's Sativex and Epidiolex. So when pharmacists supply an approved medicinal cannabis product, namely those two products, they're very easy to find dosage guidelines, evidence-based information. So pharmacists feel really confident with counseling. In the case of unapproved medicinal cannabis products, which really account for most of the prescriptions we see in Australia, there is often insufficient evidence to say to a patient, this will assist you with pain or sleep or anxiety. And I think this makes pharmacists feel out of their depth when it comes to discussing medicinal



cannabis products. Interestingly, I think as evidence grows for the therapeutic use of medicinal cannabis as a treatment, more information is developing. It's a really rapidly evolving space.

(19:54):

It's highly useful to discuss medicinal cannabis treatments with the patient. And even if you don't have a complete full understanding of why this patient isn't using it, pardon me, why this patient is using it, I think engage with someone regarding their treatment, you'll find out so much from that patient and sharing information, which is really valuable to learn, asking them about side effects or beneficial positive effects they're experiencing. Check in with the patient when they're in the pharmacy, when they're picking up perhaps their product or their repeat, discuss how their treatment's progressing or not progressing. Ask them how they're using the product because sometimes they might need a little tweak on how they're using the product or they're not getting the full benefit. So it's so important to be transparent with patients when having these conversations. It's interesting how just little things, so when it comes to medicinal cannabis dosage, sometimes ingesting it with say, a fatty meal, can actually enhance the effect.

(21:11):

And so if patients are sometimes taking it with a fatty meal, like for example, some cheese or something that's quite oily, and then another time they might not, they'll actually see variances in the way that their body handles that medication or the effect that they're receiving from it. So I think it is important to engage with the patient, and a lot of you can find a lot of information out definitely on wholesalers websites or suppliers websites, or even going directly to the manufacturer's websites, even contacting them Sometimes of course, that information is not easy to get just by click and a download. You may need to actually call the company and ask, especially if that's a particular supplier that you'll be using or a particular brand. They're often very helpful to pharmacists and they'll supply you with information that's not readily available in a public arena. They'll be very happy to help a healthcare professional with information. So yeah, don't always trust some of the things you read on unofficial websites. Of course, just like anything, you might come across information that isn't particularly correct, or it might be misleading. So it's always good to be choosy about where you get your product information from.

(22:39):

There are really great evidence-based resources and education out there for pharmacists. So for example, I'll throw some ones out there. The TGA have a medicinal cannabis landing page, which provides overviews for health professionals. There are guidelines available for using medicinal cannabis in say, epilepsy, multiple sclerosis, chronic non-cancer pain, palliative care, nausea and vomiting. There's some great resources there. Also, the Lambert Institute, which is part of Sydney Uni, I think it's linked through their Sydney Uni website, has an amazing overview of medicinal cannabis treatments and trials with links to associated web services as well, websites, nights, and of course I can't leave off. It's the Australian Center for Cannabinoid Clinical Research and Excellence, which goes by the acronym acre, ACRE. They have a great number of research articles and information about clinical trials, and they've also developed the cannabis medicines prescribing guidance to assist prescribers, mostly aimed at medical practitioners to help them with prescribing medicinal cannabis to patients for conditions which are perceived to have some benefit.

(24:11):

So it's a really rapidly evolving space. R-A-C-G-P has a great website as well that's dedicated to information for prescribers, but also I think it's useful for pharmacists to gain an understanding of the



processes behind prescribing a cannabis product, the protocols that doctors might undertake when they're thinking about trialing it in a patient where the patient might've had no success in traditional treatments and is finally at the end of almost feeling at the end of their road and they're just reaching out for help. So I think GPs are in that situation where they need guidance, and so the R-S-C-G-P has a good site there. Yeah, I think definitely trusting those sources rather than just a review website sometimes, although they can be also good for just to get a feel for what's being talked about in the circles of people using medicinal cannabis. But always, I'd recommend every pharmacist use a trusted source to gain their education or information. Yeah, so I hope that was a long-winded answer there for that question.

Speaker 2 (25:32):

That was very helpful. Thank you. And where can pharmacists seek evidence-based resources and education about medicinal cannabis to better equip themselves? Are there any other resources or evidence-based resources that you recommend?

Speaker 3 (<u>25:48</u>):

I think the ones that I was just mentioning there, they're probably my most trusted. There are definitely overseas maybe US or Canada websites that are, I mean, I think we have enough Australian based websites that we can sort of use those ones. So definitely the Lambert Initiative for Cannabinoid Therapeutics in New South Wales. There's also the John Hunter Hospital pharmacy department, which is particularly useful for assisting to understand the latest evidence around medicinal cannabis and also understanding the regulatory requirements for prescribing. But yeah, I mean the TGA are very useful too. So I think keeping eyes on all that literature as it comes out, even subscribing to updates. If you are someone that likes to have things delivered straight into your inbox, touch base with, say, some of these websites register to receive their updates or email updates, and you'll find that information is just sort of fed into your inbox.

(27:05):

If you're interested in that space and you want to further your knowledge and gain more confidence with new and emerging ways that prescribers are using medicinal cannabis. It's a very fast evolving space, and Australia is certainly embracing medicinal cannabis. When you look at where we've come from many back in, what was it, 2019 it was, or even earlier than that, I think it was a small uptake of Australian patients, but now we see a massive growth in this area. It's something that pharmacists are seeing just so much more of and being aware of the risks and knowing how to handle the storage requirements and just keeping ourselves educated at the forefront so that we know that what's happening in that space is just changing so much. It's not something that's a set and forget. It's moving rapidly. So yeah, I think those are some really great websites to follow up. If anyone listening to this podcast wants to rewind and play back those names, they will be able to find those websites pretty easily and just be able to have a great range of evidence right at your fingertips.

Speaker 2 (<u>28:28</u>):

So brilliant. Thank you. Now, are there any questions that I haven't asked you that you would like to share your thoughts about?

Speaker 3 (28:39):



There's not too much. I mean, I think there's lots of things we could talk about outside of the area of risk that we talk about with medicinal cannabis. I mean, often, sometimes I'll speak with pharmacists who sort of say to me, how do I know what a normal dose is? Or what's a typical dose of CBD or THC? How would I know that what the doctor's written is actually within a guideline? And this is bit of a fuzzy area because when it comes to starting a patient's dose, pharmacists may not really feel confident in counseling. If it's a medicine, we know, we know our antibiotics, we know what the rough dosage limits are for a child or for an adult or we sort of know in our minds what we are looking at. But when you see a script for medicinal cannabis, then it's a mixed oil or it's a flower with this or that.

(29:42):

You're thinking, well, I don't even know what that means. How much are they taking? Or how do I warn them? Just keeping in mind that most of the prescribers are asking their patients to start on really low doses, almost subtherapeutic doses. So you might see DHC doses started as low as 2.5 milligrams a day, or even lower than that, and CBD might be started around, well, I guess the recommended endpoint for CBD is the really broad range. We can go from 50 up to 1500 milligrams daily. That's the sort of dosage range With THC, it's typically the endpoint. You're sort of looking at that five to 20 milligrams total daily dose, but it's so important to start when patients are starting, always starting so low and increasing every couple of days When it comes to those slower onset oils, you want to be careful not to overload. The person's end cabin can avoid system and go too fast or too high if a slow gradual increase. And keeping, of course, patients are always encouraged to keep diaries about how they're feeling from day to day, which is really part of their journey, documenting how they're feeling to get an assessment with their prescriber if they are receiving benefit or not.

(31:15):

So drug to drug interactions is probably something we haven't touched on. That's another risk area. There is potential for interactions. CBD is an inhibitor of the cytochrome P four 50 enzymes, especially three A four, and CYP two, C1 nine. So if used in quite high doses, there are potential interactions with other medications, especially say for example, anti-epileptics or there might be medications with a narrow therapeutic window. That's something to really keep in the back of your mind as well. It's pretty rare that there is, but in high doses, there's always a chance where there can be inhibition of enzymes.

(31:59):

Contraindications always, when it comes to THC, we're always on edge about patients with a history of angina or myocardial infarction or a personal or family history of schizophrenia or psychotic related disorders. That's something that pharmacists may have a good history. You might have a history of someone's medications on your dispense system and you can see, oh, hang on. They didn't perhaps disclose that to their prescriber, and maybe the prescriber is a different prescriber to their family GP or, so those sorts of things are definitely part of our risk in the space of pharmacy where we're always on the lookout for those sorts of things. So I think, I feel like I could just talk forever about this.

(32:53):

I probably have to draw the line somewhere. Actually. Let's talk about side effects really quickly. So side effects, of course, I'm deviating away from the risk topic. I was essentially trying to aim for because I'm representing PDL, of course, side effects when it comes to CBD, which is the part of course of the non-psychoactive component. Look, I think the most commonly reported side effects are things like acute diarrhea. I think mostly the toxicity of that is it's very hard to achieve anything that's too dangerous apart from looking at that aspect of drug to drug interactions that we were talking about earlier.



However, there are definitely more side effects when it comes to THC. There are things such as acute dizziness, cognitive impairment, dry mouth nausea. There are rare psychosis, potential drug-to-drug interactions, and of course where long-term high THC use is involved. This can lead to cannabis use disorder, which is situation that is quite serious.

(34:14):

Look medicinal cannabis is generally well tolerated when appropriate doses are used. So I think it's only when, of course, if it's mixed with a street cannabis, everything starts to get quite complex then. But if you've got a patient who's adhering to the recommended amount and is willing to have a treatment journey where no one's really sure if it's going to with an unregistered non T-R-G-A-R-T-G product, you don't always know if it's going to assist that person. But it's definitely an exciting space to observe and hopefully patients will achieve some therapeutic outcome. It may not be the entire outcome that they were hoping for at the beginning, but the benefits can be there, and if done safely, it can be a really lifechanging event. For a lot of patients. I've heard some very positive stories. I mean, there's also patients out there who have tried medicinal cannabis and actually achieved almost no positive outcomes, not necessarily any negative outcomes, but just for some reason or another, it just wasn't for them. So keeping an open mind about medicinal cannabis is really important, and to recognize that for what it is, it's an emerging treatment area, lots of unknowns and with lots of unknowns. There's always risk. As we know as pharmacists, there's risk ready to appear around every corner.

(35:56):

So hope that gave a good overview there.

Speaker 2 (35:59):

Thank you. That was amazing. Thank you so much.

Speaker 3 (36:02):

You're very welcome. Thanks for having me on the show. I really enjoyed chatting, and yes, I hope anyone out there who's wanting to reach out, of course, does reach out through PDL. You're always welcome as PDL members to touch base with any of the professional officers to discuss concerns or worries regarding medicinal cannabis in your workplace. So thank you again for having me on.

Speaker 2 (36:28): Thank you. Thank Speaker 3 (36:29): You so much.

Speaker 1 (<u>36:31</u>):

We hope you've enjoyed this episode of the AJP podcast. If you have any thoughts, comments, or suggestions about this episode, please visit the AJP website forum@ajp.com.au and join the conversation. If you have any suggestions for future topics or would like to participate in the podcast, please follow us on Twitter at ajp podcast and send us a message.