PUBLIC ACCOUNTS AND ESTIMATES COMMITTEE

Inquiry into Vaping and Tobacco Controls

Melbourne – Monday 15 July 2024

MEMBERS

Sarah Connolly – Chair
Nicholas McGowan – Deputy Chair
Michael Galea
Mathew Hilakari
Lauren Kathage
Bev McArthur
Danny O'Brien
Aiv Puglielli
Meng Heang Tak

WITNESSES

Rachel Obradovic, Director, Victorian Branch, and

Jessica Seeto, Director, Policy and Regulation, Victorian Branch, Pharmacy Guild of Australia.

The CHAIR: I declare open this hearing of the Public Accounts and Estimates Committee. I ask that mobile telephones now be turned to silent.

On behalf of the Parliament, the committee is conducting this Inquiry into Vaping and Tobacco Controls.

I advise that all evidence taken by the committee is protected by parliamentary privilege. However, any comments repeated outside of this hearing may not be protected by this privilege.

Witnesses will be provided with a proof version of the transcript to check, and verified transcripts, presentations and handouts will be placed on the committee's website.

I welcome you, Rachel Obradovic – close; there have been some tricky ones today – Director, and Jessica Seeto, Policy and Regulation Director, of the Pharmacy Guild of Australia, Victorian Branch. I am going to invite you to make an opening statement or presentation of no more than 5 minutes, and then the committee will ask you some questions. I will hand over to you.

Rachel OBRADOVIC: Thank you. The Pharmacy Guild of Australia, Victorian Branch, welcomes the opportunity to give evidence to the Parliament of Victoria Public Accounts and Estimates Committee Inquiry into Vaping and Tobacco Controls. The guild is the national employers organisation representing and promoting the value of community pharmacy in the Australian healthcare system. For more than 90 years the guild has supported community pharmacy in its role of delivering quality healthcare outcomes for all Australians. Today, as we did in our submission to the inquiry, the guild will focus on the effectiveness of current public health measures to prevent and reduce the harm of tobacco use and vaping in Victoria and potential reforms. However, since making our submission earlier this year there have been significant changes to Commonwealth legislation restricting the sale of vapes in Australia. It is in this context the guild provides evidence today.

The *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* passed the Commonwealth Parliament in late June. It makes vapes available for purchase over the counter without a prescription in a community pharmacy. This will be achieved by moving nicotine-containing vapes from prescription-only schedule 4 to pharmacist-only schedule 3 medicines from 1 October this year. This will make nicotine vapes the only unapproved product supplied as a schedule 3. The guild strongly opposes the Commonwealth reforms, which compromise community health and do not take into consideration the safety concerns or lack of proven efficacy of vapes as a smoking cessation device.

There are several reasons why the guild opposes the Commonwealth vaping reforms, but at the crux of this pharmacists are healthcare professionals who dispense medication that has a proven therapeutic benefit. On the available evidence nicotine vapes do not fall into this category. There is currently limited evidence to support the use of vaping products for smoking cessation and nicotine dependence. Vaping products have not been approved by the Therapeutic Goods Administration, and no nicotine-containing vape is listed on the Australian Register of Therapeutic Goods. There are also unknown long-term patient harms and a high level of involvement from big tobacco companies. The provision of unapproved nicotine vapes without prescription legitimises a product that may be causing harm with unknown long-term health consequences.

It is also uncertain whether pharmacist professional indemnity insurance covers the supply of a vaping product without prescription. Further work is required to ensure there are no legal liabilities for healthcare professionals who prescribe, compound and dispense unapproved vapes for therapeutic use where the patient has made an informed decision regarding their treatment.

Furthermore, the guild is concerned about how vaping reform legislation will be enforced, including stopping the sale of illegal vapes and protecting community pharmacies, who have now been brought into the front line. We understand that enforcement is a state responsibility. However, there is detail lacking around how this will play out.

As stated in our inquiry submission, the guild advocates for the supply of smoking and vaping cessation products in the community to be regulated. The guild supports vaping and tobacco control complementing appropriate evidence-based smoking and vaping cessation treatments which meet the varying needs in the community. Single-use devices pose the maximum threat of being appealing to adolescents and children, and there should be no exception for these devices to be available in Australia.

We acknowledge too that as Australia's most successful primary health care providers community pharmacies play an important role in the prevention and reduction of the harm from tobacco use and vaping in Victoria. Pharmacists and pharmacy staff assist smoking cessation in several ways, including by providing advice around quitting and advice and support on nicotine replacement therapy and other evidence-based products.

Nicotine-containing vapes are indicated for smoking cessation and treatment of nicotine dependence only when other evidence-based treatments have failed. To this end their classification as a schedule 4 medicine available by prescription only is appropriate. The guild's position is that the only legal access to nicotine-containing vapes is through the community pharmacy on receipt of a valid prescription following a consultation between a patient and a prescriber. However, should the reclassification of nicotine vapes as schedule 3 medicines proceed from 1 October, the guild believes these products should be required to be on the Australian Register of Therapeutic Goods. Guidelines must then be established for pharmacists to follow if they do conduct a patient consultation for the supply of nicotine vapes. To this end, the guild has previously advocated to the TGA that the treatment period of nicotine vapes as a smoking cessation aid should be limited to 12 weeks, consistent with other nicotine replacement therapies.

We urge the Victorian government to support patients motivated to cease smoking or vaping through greater access to evidence-based treatments for nicotine dependence. This includes rejecting the reclassification of nicotine as schedule 3, working with the guild to determine a solution that prevents vapes falling into the hands of children while respecting pharmacists' roles as healthcare professionals who dispense medication providing a therapeutic benefit, granting pharmacists prescribing rights for smoking cessation treatments, amending clinical criteria for these listings to recognise them as treatments for the cessation of nicotine vaping and ensuring nicotine-containing vapes are only recognised as therapeutic goods if they are included on the Australian Register of Therapeutic Goods. The guild will always seek a solution that enables pharmacists' role as healthcare professionals delivering quality healthcare outcomes for all Australians. We look forward to working with the Victorian government to optimise smoking cessation management based on the contemporary clinical evidence and safety protocols available for therapies. We thank you again for the opportunity to participate in today's inquiry.

The CHAIR: Thank you so much. We will go straight to Mrs McArthur.

Bev McARTHUR: Thank you so much. You have provided a very erudite presentation of the real issue we are facing. Was the pharmacy guild consulted before the federal government announced that you would become tobacconists?

Rachel OBRADOVIC: No. We were not consulted, no.

Bev McARTHUR: No. No consultation whatsoever. Well, that does not seem appropriate, does it?

Rachel OBRADOVIC: We would agree; no, it is not appropriate.

Bev McARTHUR: Okay. So what would you say is the best way to get people off this product that is so harmful?

Rachel OBRADOVIC: Let us talk about replacement therapies.

Jessica SEETO: I guess there are evidence-based therapies that are used for smoking cessation that are proven, that are on the register of therapeutic goods. So you have got your nicotine replacement therapy, the traditional type, and you have also got some prescription-only medications that GPs can prescribe for smoking cessation as a pharmaceutical benefit. So I think there are more effective ways that people who are looking to cease smoking or cease vaping could be helped by the government. In Queensland there is a smoking cessation community pharmacy pilot that enables pharmacists to do more for patients. With these reforms pharmacists will not be able to do, I guess, all of the work around helping people quit smoking, so they would potentially

have to refer patients back to the doctor if they did genuinely want to cease smoking or need management for nicotine dependence and want an evidence-based treatment. Enabling pharmacists to be able to prescribe treatments that are already on the pharmaceutical benefits scheme would be more effective.

Bev McARTHUR: Can I just ask: how many pharmacists do you think will involve themselves in rolling out the selling of products over the counter?

Rachel OBRADOVIC: It is a good question. It is not mandatory for pharmacists to stock these as a schedule 3 medicine –

Bev McARTHUR: Right.

Rachel OBRADOVIC: and at the time that the announcement was made, the pharmacy guild, the Pharmaceutical Society of Australia and a number of the other banner groups did come out and say that they will not be stocking and selling those products as a schedule 3 medicine.

Bev McARTHUR: So clearly it will fail, that proposal. We heard also from the young people and the education sector here earlier that primary school aged children are perhaps using vapes – and where would they get them from? Well, maybe in a household. So would you see that as a problem, if you are providing vaping products over the counter to an adult, that they might be left lying around in a household for a young person to use?

Jessica SEETO: Yes, that is always a risk with any type of medicine.

Rachel OBRADOVIC: Pharmacists will only be able to provide, under the regulation, to those who are aged 18 and over, but as I think Jess has just alluded to, that is a risk with all sorts of products that are in a household.

Bev McARTHUR: Tell us about the insurance issue that you are going to face.

Jessica SEETO: There are a number of different issues with regard to insurance. You have got professional indemnity insurance that pharmacists are required to have as part of their registration. It is unclear at this point whether or not pharmacists will be covered by that insurance to supply an unapproved good, so the guild has sought legal advice on that. And then you have also, I guess from the other perspective, premises insurance on a pharmacy – you know, pharmacies could become a target for attacks if they are keeping vapes, so that is likely to increase the cost of insurance. So that is probably a deterrent for people to actually keep them. But you could still be a target without stocking them, so it is going to have these impacts on both the professional and also on the pharmacy.

Bev McARTHUR: So this proposal that the federal government have rolled out is clearly not going to work. You are not going to supply the product, or a majority of your members are perhaps not going to supply the product, so what do you suggest – that the government give it the flick and start again?

Rachel OBRADOVIC: At the time that the debate went through, we were not in the debate. Our position was, 'It's not a schedule 3 medicine, it's not a debate that we need to be in.' As a product that was being prescribed, we were part of that process. I think there was a view that that needed more time, to see if the prescriber model was an effective use. But at this point in time, there are no vapes that have been listed for therapeutic purposes, and that is a concern for us downgrading it to a schedule 3 medicine.

Bev McARTHUR: So unless the government could get them on the Therapeutic Goods Administration tick list, they are a problem?

Rachel OBRADOVIC: That would be our position, yes.

The CHAIR: Thank you. Mr Galea.

Michael GALEA: Thank you, Chair. Thank you both for joining us today. You have put a very good case forward, and as you have also noted, it will not be mandatory for pharmacists to dispense vapes. Just noting the very important role pharmacists play in local communities – I will give a shout-out to my pharmacist Louisa – and the role that they play in providing that very much frontline health support for all sorts of different issues. If

pharmacists do not engage with this, then the people who would otherwise have that opportunity to talk with their local pharmacist to get that support they might not even realise that they needed by going to them for a vape – is there a risk that that might be missed?

Rachel OBRADOVIC: I do not think so. As Jess said earlier, and we will go back to it, there are currently smoking cessation products available that have been approved, which I will get Jess to talk about more, where we think that there is actually real scope for pharmacists to actually engage with patients and support them in quitting smoking through other proven methods.

Jessica SEETO: And I think you have to recognise that people that genuinely want to quit will be inclined to come and speak to a healthcare professional. I think there is the recreational use, and there will still be those people wanting vapes for recreational use, but those with a genuine desire to quit will engage with their health professional.

Michael GALEA: I guess I am perhaps more thinking of those people that may be falling into a problem without realising it, thinking that they do not have a problem. By having to go and talk to their pharmacist and start that conversation, the pharmacist might say to them, 'Well, hang on, you have been here a few times for this now, let's have a conversation about this.' Is there any potential for that to actually help people out of vaping, through their pharmacist?

Jessica SEETO: One of the concerns with regard to your statement is they may be coming a few times, so they potentially could go to any pharmacy. There is no recording as part of the federal legislation, so pharmacists will not have oversight of how often these people are accessing vapes. So yes, ideally, if someone is coming in, then you would have that conversation. That is not to say that they will not come into a pharmacy to see if you do stock vapes, and you can still have that interaction.

Michael GALEA: So as far as you are aware, and based on what has been said to you, there is going to be no reporting mechanism like there is for some other –

Rachel OBRADOVIC: That is our understanding. That is right. Our understanding is that the expectation is to provide – I think, Jessica – a month's supply, but there is no way of recording that, no way of seeing if someone has tried to get a month's supply from alternative pharmacists and therefore has got multiple of these devices.

Mathew HILAKARI: Will pharmacists use every opportunity anytime somebody comes in? Let us say their pharmacist is selling vapes and they come in for that month's supply, isn't that the opportunity every time to then talk about other options as well as vaping? I would have thought that is a great opportunity to engage people in what you described as proven methods. Wouldn't that opportunity be better taken than not had at all?

Jessica SEETO: I guess from our position, as an S4 medicine, they would be speaking to their doctor.

Mathew HILAKARI: Those times have changed. But isn't this an opportunity for pharmacists to actually deliver some of that great health care that pharmacists provide in so many other areas?

Jessica SEETO: It would be, but I guess the issue is that there is not a lot that we can then do, other than have that conversation. Nicotine replacement therapy over the counter is quite expensive, so it can be quite unaffordable; unless it is as a pharmaceutical benefit, pharmacists will not be able to prescribe as a pharmaceutical benefit.

Mathew HILAKARI: So seeing your doctor, which sometimes costs maybe $80 to go see your doctor to get a script, as the old method was, that is probably a saving straight up for people then to have that conversation with pharmacists and maybe put that money towards some of what you have described as proven methods.

Jessica SEETO: Yes. You are looking probably at a week's worth being maybe about the $35 mark. So it can get quite expensive.

Rachel OBRADOVIC: The issue there would be working with the state government around what pharmacists' roles can be via scope of practice in order to come up with a model whereby, yes, we could do that but ensure that the availability of the current existing proven products is not cost-prohibitive.

Mathew HILAKARI: So it is really actually down to a dollar thing, you are saying, rather than a pharmacist being available to talk through what is in the best interests of the patient. It is, 'We're not currently provided funding for this, so therefore we probably really aren't going to be able to and would prefer that in a different place.'

Jessica SEETO: No, I do think it just comes down to cost. They are not proven therapies.

Mathew HILAKARI: But you are happy at a schedule 4 level to say that they are proven enough for a doctor –

Rachel OBRADOVIC: At a schedule 4 level it is on a prescription basis where they have had a conversation with their GP, and the idea of a schedule 4 on a prescription basis is that it is a last resort. It is to a point where other methods have been tried and have not prevailed and have not worked, and we are at this point now where shifting it from that to a schedule 3 medicine shifts that conversation away to it simply being prescribed as an over-the-counter medication. Yes, the conversation can still be there, but for a pharmacist under the current model to have the ability to really work through what the other treatment methods might be before we get to an unproven product would need a referral back to a GP in order for them to receive them with the Pharmaceutical Benefits Scheme.

Bev McARTHUR: Can I just butt in here. Have pharmacists got the time and the ability to provide medical advice to a potential patient where they do not know anything about their other history?

Rachel OBRADOVIC: Pharmacists' role in the community is to provide this sort of advice to patients on proven medications with a therapeutic good. It is what they see their role as doing. It is very hard with this one where there is no evidence that these devices do work for the purpose of smoking cessation, and that I think is the challenge there. I would not want to go as far as saying, 'No, they don't have the time.' They are small business owners. They are very time-poor, but particularly in rural and regional Victoria they do look after their patients. They are on the front line of the provision of community health care. So to outright say, 'No, they don't have the time to have these conversations –'

Bev McARTHUR: Or the ability.

Rachel OBRADOVIC: But it is more that these goods are not proven to actually achieve the purpose that we are wanting to see here, which is the smoking cessation tool.

Jessica SEETO: And it is quite a lengthy consultation that pharmacists are being asked to undertake as part of this schedule 3, so essentially doing the work of the GP but in the pharmacy.

The CHAIR: Michael, I think you had one last question.

Michael GALEA: No, that is fine. In light of time I will yield the rest. Thank you.

The CHAIR: Okay. Mr Puglielli.

Aiv PUGLIELLI: Thank you, Chair. Thanks for coming. I might just pick up where we left off, so the idea of doing the work of a GP. The previous federal proposal prior to the amendment that saw it go through the chamber, where it was a prescription model for accessing these products – who is it at the end who dispenses that product?

Jessica SEETO: Up until now there have been two different pathways, so either through a community pharmacy or the personal importation scheme. For the majority of people, they have been using the personal importation scheme.

Aiv PUGLIELLI: Sure, but for some there will be at the end, even if that model has been implemented, a pharmacist dispensing that product to the consumer.

Jessica SEETO: Yes.

Aiv PUGLIELLI: Okay. So I suppose given that, and given where we have landed, where it is schedule 3 – I mean, really, in terms of the role of the pharmacist in that picture, what has changed?

Jessica SEETO: This is the only unapproved good that is supplied as a schedule 3 medicine. There are lots of pathways for unapproved products to come into the country, but they follow, I guess, defined pathways through the Therapeutic Goods Administration. That is what has changed, that whole landscape of supplying an unapproved product as a schedule 3 medicine without a prescription – it is the only medicine supplied as an unapproved schedule 3.

Aiv PUGLIELLI: Okay, okay.

Rachel OBRADOVIC: So what that means is that the Therapeutic Goods Administration has not listed any of these products to be registered on the Australian Register of Therapeutic Goods, which means that there is nothing proven that it is a medical device – there has been no research; there is no efficacy around it – whereas other schedule 3 medications do have that; they do have those approvals. That is the difference. So you are asking pharmacists to effectively provide a product that has not gone through the processes to say that there is a therapeutic benefit here, whereas all the other schedule 3 medicines have.

Aiv PUGLIELLI: Okay. Just to make sure I have understood correctly, though: the previous proposal, where it was a prescription medication from a GP – were you approving of that model?

Jessica SEETO: We did support schedule 4. We thought that it was appropriate for it to be on prescription like other unapproved goods with consultation with a GP, who can then offer a broader range of treatments that have evidence behind them.

Aiv PUGLIELLI: Right. See, this is the thing I am just trying to get my head around. So you would be supportive of it if it were a schedule 4 from a GP, even though it is not listed on the TGA, but it is an issue when it is schedule 3?

Rachel OBRADOVIC: Correct.

Jessica SEETO: Yes.

Aiv PUGLIELLI: Can you clarify that a bit more for me? That does not quite make sense.

Rachel OBRADOVIC: Just the understanding that it would not be the only schedule 4 medication.

Jessica SEETO: It is the only schedule 3 that is unapproved, so –

Rachel OBRADOVIC: It is not the only schedule 4, is that right?

Jessica SEETO: That is right, yes. There are other schedule 4 medicines that are not approved and, as I said, follow the defined pathways through the TGA. But I guess one of the issues is that pharmacies cannot then provide other treatment options for patients. A GP writing on a prescription could say, 'There's a better evidence base for this prescription medicine. I'll supply you with that instead.' I think it is about the patient getting holistic care.

Aiv PUGLIELLI: Right. It just feels a little bit arbitrary that the TGA consideration is not a concern if it was schedule 4 but it is for schedule 3, when at the end it may be that pharmacists dispense it anyway. I appreciate that you are going into detail to clarify it, though. The other nicotine cessation products that you do stock, I believe – just correct me if I am wrong – are schedule 2. Is that how you classify it?

Jessica SEETO: They are actually unscheduled.

Aiv PUGLIELLI: Unscheduled. Okay. So those are not listed by the TGA, or they are?

Jessica SEETO: They are. They are on the Australian Register of Therapeutic Goods.

Aiv PUGLIELLI: Okay. All of them?

Jessica SEETO: Yes.

Rachel OBRADOVIC: They are, yes.

Aiv PUGLIELLI: Good to know. And just clarifying as well, in terms of access to the product: even in the current form that has passed through Parliament, those under the age of 18 are still accessing it via prescription from a GP, so you may still be in the scenario of dispensing to someone under-age – just so we make sure that we paint the picture properly of instances where you might be dispensing these products.

Jessica SEETO: That is the federal legislation. There is state and territory legislation that potentially contradicts that in terms of the *Tobacco Act* as to whether or not a patient under the age of 18 can be dispensed a vaping product on a prescription, so we are currently trying to understand those complications as well.

Aiv PUGLIELLI: Yes. Could you talk about that in a bit more detail? What is the conflicting issue?

Jessica SEETO: There is the tobacco legislation and the therapeutic goods legislation, and they do not marry up at this point. In some states and territories you are actually prohibited from supplying a vaping good to a patient under the age of 18 with a prescription. So even if a doctor writes a prescription, there could be other legislation that prohibits the pharmacist from actually dispensing it.

Aiv PUGLIELLI: Right. So would you say there might be a need for Victorian legislative change to actually implement the federal policy that has just come through?

Rachel OBRADOVIC: Potentially.

Jessica SEETO: Potentially, yes.

Aiv PUGLIELLI: Okay. That is really valuable. Thank you. I might just leave it there. Thank you, Chair.

The CHAIR: Great. Thanks, Mr Puglielli. Mr Tak.

Meng Heang TAK: Thank you, Chair. Just one question from me. Do you believe that the general population has adequate access to understanding the impact of harm from vaping and e-cigarettes? If not, what more can be done to increase awareness and promote behaviour change?

Jessica SEETO: There have not been a lot of public health campaigns on vaping. Obviously in more recent times maybe governments are putting more resources into it, but I think probably more funding needs to go into research to actually understand the long-term harms. I think potentially having them as a therapeutic product is legitimising a product that we do not know what the long-term consequences of are.

Rachel OBRADOVIC: And that is one of our concerns that we stated earlier – that it is potentially legitimising quite a harmful, dangerous product.

Aiv PUGLIELLI: Sorry, to just follow on from before – if it was on schedule 4, though, that would not have been an issue.

Rachel OBRADOVIC: Again, with the schedule 4 medication the expectation is it has been prescribed by a GP, that it is a last resort and that the GP has had the opportunity and the patients have had the opportunity to use other nicotine-replacement therapies that are available that are evidence based before it has got to a point where it is even prescribed.

Aiv PUGLIELLI: Right. Thank you. Sorry to jump in.

Meng Heang TAK: Okay. Thank you, Chair.

The CHAIR: Mr Hilakari.

Mathew HILAKARI: Just a final one. I know you mentioned previously that there is an opposition to this. I am just wondering about the percentage of pharmacists who actually currently supply that you are aware of or have indicated to the guild that they intend to supply vapes – or it is all too early. It could be all too early.

Jessica SEETO: We do not have the information available.

Rachel OBRADOVIC: I would actually have to take that one on notice, because they are small business owners. What has come forward is the larger banner groups have said that they will not, but understanding the independents that might, we would have to take that on notice and see what has come through to us.

Mathew HILAKARI: I understand it is totally early days and a very changing situation.

Rachel OBRADOVIC: Yes, it is early. And look, for context, the groups that have come forward and indicated that they will not be providing them are groups such as Pharmacy 777, Blooms have come forward –

Jessica SEETO: TerryWhite Chemmart, Priceline.

Rachel OBRADOVIC: TerryWhite Chemmart and Priceline. So we are talking a large number that have said no, but in terms of any of the more independent, smaller ones, we would have to take it on notice and see what has come through.

Mathew HILAKARI: On notice is fine. Thank you so much. We really appreciate it.

Rachel OBRADOVIC: No worries. That is okay.

The CHAIR: Thank you, Mr Hilakari. That brings our time together this afternoon to an end. Thank you so much for taking the time to come and talk to us.

Rachel OBRADOVIC: Thank you for having us.

The CHAIR: The committee will follow up on any additional questions or questions taken on notice in writing, and responses are required within five working days of the committee's request.

The committee is going to take a very short break before recommencing the hearing. I declare this hearing adjourned.

Witnesses withdrew.