Health Committee

Komiti Whiriwhiri Take Hauora

54th Parliament March 2024

Misuse of Drugs (Pseudoephedrine) Amendment Bill

21—1

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Misuse of Drugs (Pseudoephedrine) Amendment Bill

Recommendation

The Health Committee has examined the Misuse of Drugs (Pseudoephedrine) Amendment Bill and recommends that it be passed without amendment.

About the bill as introduced

The Misuse of Drugs (Pseudoephedrine) Amendment Bill proposes to change the classification of pseudoephedrine as a controlled drug. The bill would amend the Misuse of Drugs Act 1975 to reclassify pseudoephedrine from a Class B2 to a Class C3 controlled drug.

The Medicines Regulations 1984 (under the Medicines Act 1981) have already been amended to reclassify cold and flu medicines containing pseudoephedrine. This change will come into effect on 21 March 2024.

The combined result of these two reclassifications means pseudoephedrine cold and flu medicines would shift from being prescription-only to restricted, pharmacist-only. The purpose of the reclassifications is to make pseudoephedrine cold and flu medicines more widely available by enabling registered pharmacists to sell them without requiring a prescription.

Pseudoephedrine would remain a controlled drug, so border restrictions would remain unchanged. A licence would still be required to import or export products containing pseudoephedrine.

The bill would also make some minor amendments to the Misuse of Drugs Regulations 1977, to ensure that any references to pseudoephedrine align with the policy intent of the bill.

Background and history of the regulatory settings

Before 2004, cold and flu medicines containing pseudoephedrine could be purchased over the counter from pharmacies. In 2004, due to concerns about its use in the manufacture of methamphetamine, pseudoephedrine was classified as a controlled drug under the Misuse of Drugs Act. In 2011, pseudoephedrine was further restricted and became a prescription-only medicine under the Medicines Act.

This bill would re-create the regulatory environment that existed between 2004 and 2011. Pseudoephedrine would be available for sale in pharmacies but only by a registered pharmacist.

Legislative scrutiny

As part of our consideration of the bill, we have examined its consistency with principles of legislative quality. We have no issues regarding the legislation's design to bring to the attention of the House.

Main themes raised by submitters

We received submissions from 169 individuals and 9 organisations. Most organisations, including pharmaceutical industry bodies and drug harm prevention groups, indicated support for the bill in their submissions.

We are not recommending any amendments to the bill as introduced. We discuss below the main themes raised by submitters.

Pseudoephedrine is a precursor for methamphetamine

Pseudoephedrine can be used to manufacture methamphetamine. The primary concern of submitters who oppose the bill is that increased availability of pseudoephedrine products will increase the supply and availability of methamphetamine.

Many submitters acknowledged the harm caused by methamphetamine and were concerned about reducing both use and harm. This was true both for submitters who support the bill and those opposed.

Supply and availability of methamphetamine has increased since 2011

Many submitters observed that the supply and availability of methamphetamine has increased since 2011. They told us that the measures introduced in 2011 failed to address demand for methamphetamine, and the market responded by importing higher-efficiency precursors and finished methamphetamine products from overseas. Drug policy experts stated that criminal groups became more sophisticated and formed relationships with global drug trafficking networks.

One submitter explained that 27.8kg of pseudoephedrine medication is needed to manufacture 1kg of pure methamphetamine. In contrast, only 1.75kg of a higher-efficiency precursor is needed for the same yield. According to the submitter's estimates, someone would need 2,430 packets of pseudoephedrine medication to make 1kg of methamphetamine.

Price of methamphetamine has decreased since 2011

Another submitter informed us that the nominal price of methamphetamine has dropped by 40 percent. Several other submitters reiterated the message that methamphetamine availability has increased, and price has decreased.

Submitters said that pseudoephedrine products are of little value to people interested in commercially supplying methamphetamine, as there are now cheaper and easier ways to manufacture it. In their view, this means that making pseudoephedrine products more available will have little effect on New Zealand's illicit drug market.

This position was supported by advice we received from the Ministry of Health, which consulted with the New Zealand Police, the New Zealand Customs Service, and the National Drug Intelligence Bureau.

Small-scale domestic methamphetamine production may increase

We received evidence that commercial manufacturing of methamphetamine is unlikely to increase as a result of this bill. However, we note submitters' concern that small-scale

domestic production by individuals may increase. We recognise that even a small increase in methamphetamine use is worrying for individuals, families, and communities.

We heard from submitters with lived experience of methamphetamine use. They described the lengths that addicted people will go to obtain methamphetamine. We heard that addicted people will form syndicates and work together to get around the restrictions on sale, such as the requirement for a pharmacist consultation.

Harm caused by methamphetamine

Submitters opposed to the bill argued that the medicinal value of pseudoephedrine is outweighed by the harm of potentially increasing methamphetamine supply. Some submitters highlighted that methamphetamine use is higher in Māori, Pasifika, and rural communities, and that these communities would be disproportionately harmed by increasing the availability of pseudoephedrine.

Submitters supportive of the bill argued that that there is no evidence that methamphetamine harm has reduced since restrictions on pseudoephedrine were tightened in 2011. One submitter told us that deaths involving methamphetamine have increased from 19 deaths in 2009 to 130 deaths in 2017.

Reducing methamphetamine harm

We support programmes to reduce drug harm. One submitter highlighted the success of Te Ara Oranga, a methamphetamine harm reduction programme in Northland.

We learned that more than one in five people with a substance use disorder meet the criteria for ADHD. We were told that increasing access to diagnosis and treatment of ADHD among illicit stimulant users decreases demand for methamphetamine. We encourage the Ministry of Health and Health New Zealand—Te Whatu Ora to explore avenues for improving timely diagnosis and treatment of people with ADHD.

Crime and the safety of pharmacists

Many submitters were concerned that pharmacies will become a target for criminal activity. Submitters worried that there may be an uptick in thefts, ram raids, and aggravated robberies, and that pharmacists' safety may be compromised.

We note that pharmacies will not be required to stock pseudoephedrine products, and we support pharmacists' right to make this choice. We rely on pharmacists to make judgements about what is best for them and their customers. We also note that the Pharmaceutical Society of New Zealand, which represents 2,000 pharmacists, submitted in favour of making pseudoephedrine more available to patients.

Control measures

We acknowledge submitters' concerns regarding crime, and support reasonable and practical prevention measures. We sought advice about various control measures including storage requirements, tamper-resistant products, ¹ and monitoring methods.

Products that can be inserted into pseudoephedrine medicine to make it harder to extract pseudoephedrine for manufacture of methamphetamine. These are sometimes known as "binders".

Tamper-resistant pseudoephedrine products

One submitter with experience of methamphetamine use told us that "binders" can be mixed into pseudoephedrine products to make it harder to manufacture methamphetamine. The evidence presented to us on the effectiveness of tamper-resistant products was not conclusive. We were also advised that requiring pseudoephedrine products to contain tamper-resistant technology is not practicable, as there are not enough commercially available products of this type.

Monitoring the sale of pseudoephedrine products

We think it is important that the sale and purchase of pseudoephedrine products is monitored. We see value in a national electronic register to track the sale of products and help pharmacists identify bulk buying.

We understand that Australia has a real-time monitoring system, and sought advice about the practicability of implementing something similar in New Zealand. We were advised that, under existing regulations, pharmacists are already required to record information such as the buyer's name and address for the sale of restricted medicines.

However, pharmacists are not required to use an electronic dispensing system to process the sale; this limits the ability for live, nationwide monitoring. Electronic dispensing systems produce a unique identifying number for the sale, and record this information in a centralised system. A system that already exists is the New Zealand ePrescription Service (NZePS). We were advised that pharmacists are increasingly adopting electronic dispensing systems and that vendors are improving functionality of NZePS to allow pharmacists access to patient history, including past sales of pseudoephedrine products.

We were pleased to learn that the Ministry of Health is working with Health New Zealand—Te Whatu Ora to explore options for improving the uptake and standardisation of a nationwide electronic dispensing system. We view the implementation of a monitoring system as an important harm mitigation tool. We were assured that this work is under way.

We plan to follow up with the Ministry of Health and Health New Zealand—Te Whatu Ora on this. We expect to receive an update on how they are progressing with the implementation of a monitoring system by the end of 2024.

Medicinal value of pseudoephedrine

Many submitters commented that pseudoephedrine is effective at relieving the symptoms of colds, flu, asthma, and hay fever. Submitters told us that pseudoephedrine is internationally recognised as a low-risk medicine and is sold over the counter in countries like Australia, USA, United Kingdom, and much of Europe.

Several individuals who suffer from chronic sinus issues described to us the personal clinical benefit they would gain from being able to access pseudoephedrine more easily. Other submitters pointed out that while pseudoephedrine relieves symptoms, it is not a cure and does not shorten recovery time. Submitters raised concerns that unwell people might return to work while still infectious because they felt better.

Current availability of pseudoephedrine

Several submitters suggested that keeping pseudoephedrine as a prescription-only medicine is a good compromise between making medicine available to people who need it and safeguarding against misuse. However, we heard that, in practice, people rarely visit a doctor when they have a cold or flu, and that GP consultation fees are a barrier to accessing medicine.

We were advised that, while pseudoephedrine is technically available by prescription, there are currently no active approvals for pseudoephedrine products in New Zealand. Under the current settings, the market for pseudoephedrine is so small that drug companies have let their product approval licences lapse and no longer import products.

One submitter cited research that demonstrated the positive economic value of self-care. They told us that appropriate self-care can reduce pressure on primary health care providers.

Consultation period

Many submitters were concerned about the length of the bill's public consultation period. Several submitters felt the process would have benefited from more time to carry out engagement. This feedback was received during the consultation period and the Chairperson agreed to extend the time for written submissions.

Comments from the Associate Minister of Health

We held a hearing with the Minister responsible for the bill, the Associate Minister of Health, Hon David Seymour. The Minister's comments echoed many of the themes raised by submitters. He emphasised that marketplace conditions mean it is no longer economically viable to use pseudoephedrine obtained from a pharmacy to manufacture methamphetamine. He also emphasised that, while pseudoephedrine would be more available under the proposed legislation, it would still be tightly regulated.

The Minister noted that, while Cabinet has agreed to the reclassification of pseudoephedrine, Medsafe would still independently approve pseudoephedrine products before they can legally be sold in New Zealand.

New Zealand Labour Party differing view

The extremely shortened select committee process means the Labour Party cannot commit to a position on this bill in time for inclusion in this report. We do however wish to note here our concerns relating to the select committee process and the content of the bill.

We are concerned the truncated process for submissions and hearings means many members of the public would not have time to submit to the committee, and that the committee has therefore missed the opportunity to hear valuable evidence and resolve currently unresolved questions. It was evident in our hearing that Ministry of Health policy development processes were also truncated, and only a small number of pharmacy representatives were engaged with in the course of advising the Minister. Furthermore, pieces of evidence presented by the Ministry were not synthesised. This included the

evidence on binders which are additives to pseudoephedrine tablets which could potentially inhibit the production of methamphetamine from the compound. The committee has not had clear advice on whether they are effective.

Our view is that pseudoephedrine is helpful for management of cold symptoms and the convenience of over-the-counter purchase is a desirable outcome, if appropriate mitigations and harm reduction approaches were taken to reduce the risk of it being used to produce methamphetamine. As noted in the Drug Foundation's submission, the low cost of imported methamphetamine relative to that made domestically does not guarantee that domestic production of meth from pseudoephedrine will not happen. There will be individuals whose personal circumstances will favour methamphetamine production from pseudoephedrine; for example, people with addiction could do so out of desperation. Therefore, mitigations are required.

The mitigations raised with the committee include:

- scaling up of successful programmes for treating addiction, such as Te Ara Oranga
- better access to treatment for those with ADHD who are over-represented among people with substance disorders
- the need for real-time monitoring of pseudoephedrine sales, as occurs in Australia, to quickly identify instances of people purchasing at multiple pharmacies to produce methamphetamine
- a requirement to limit the quantity of pseudoephedrine held in pharmacies and/or to keep it in a safe.

We do not have confidence that these mitigations are occurring, or if they are, not at the scale required. While the committee has been advised that Te Whatu Ora is developing IT infrastructure that could track pseudoephedrine purchases, we have had no assurance of when that programme will be complete, or whether it would be used for real time monitoring once developed.

We are also concerned by the view expressed by the ministry that it is impractical to require pharmacists to store stock in a locked safe, because of the quantities involved. The quantities involved is precisely why they must be stored securely. While our colleagues argue pharmacists are free to take that risk, the impacts of break-ins are not just on pharmacy owners, and our regulation of other drugs reflects that.

In conclusion we support the intent of the bill but have concerns that an expedited process has meant many sensible mitigations have not been adequately pursued.

Comments from the Associate Minister of Health

Given the Minister's statements that the public interest justifying the fast-track of this bill through the House and select committee is "an additional winter, so long as the pharmaceutical companies and Medsafe play ball" we think it is important to show more fulsomely the Minister's rationale as explained to our committee. Therefore we would replace the paragraph "Comments from the Associate Minister of Health" with the paragraphs below:

We held a hearing with the Minister responsible for the bill, the Associate Minister of Health Hon David Seymour. The Minister confirmed that the

classification was done at a ministerial level and by Cabinet and that Medsafe retained the right to refuse to consent any applications from pharmaceutical companies if it determined that it was inappropriate for its classification to be downgraded from prescription-only to restricted. He stated that the current classification was arguably a political decision and with hindsight was wrong. He mentioned harmonising New Zealand's regulations with comparative countries such as Five Eyes as a compelling reason for the reclassification.

The Minister said that marketplace conditions meant it was no longer economically viable to use pseudoephedrine obtained from a pharmacy to manufacture methamphetamine. The Minister stated that it was better to focus on the information available about the manufacturers of meth who were the target of the pseudoephedrine ban rather than seek further advice on the communities impacted by meth. He said those manufacturers were "extremely rational actors" and therefore it would be irrational to think that people would continue to manufacture in the way that they did previously.

The Minister said organised shopping for pseudoephedrine was a potential problem and that regulations requiring sales registers to be collected from pharmacies had previously been found to be ineffective. He would monitor sales this winter to see whether a regulatory system was justified however he would not waste taxpayer money on a system if it did not work.

Green Party of Aotearoa New Zealand differing view

The Green Party of Aotearoa New Zealand also shares the concerns of the Labour Party. The Green Party of Aotearoa New Zealand affirms an ongoing desire to see a full review of the Misuse of Drugs Act.

Appendix

Committee procedure

The Misuse of Drugs (Pseudoephedrine) Amendment Bill was referred to the Health Committee of the 54th Parliament on Tuesday, 20 February 2024. Submissions opened on Wednesday, 21 February with a closing date of Monday, 26 February. The period for submissions was extended on Tuesday, 27 February until Friday, 1 March 2024.

We received and considered submissions from 169 individuals and 9 organisations. We heard oral evidence from 13 submitters at hearings in Wellington and by videoconference.

We received advice on the bill from the Ministry of Health. The Office of the Clerk provided advice on the bill's legislative quality.

Committee members

Sam Uffindell (Chairperson)
Dr Hamish Campbell
Dr Carlos Cheung
Ingrid Leary
Cameron Luxton
Hūhana Lyndon
Jenny Marcroft
Debbie Ngarewa-Packer
Hon Dr Ayesha Verrall

Related resources

The documents that we received as advice and evidence are available on the <u>Parliament</u> <u>website</u>.