Regulatory Impact Statement: Allowing sales of cold medicines containing pseudoephedrine

Coversheet

Purpose of Document	
Decision sought:	Agreement to amend the Misuse of Drugs Act 1975 to reclassify pseudoephedrine from a Class B2 controlled drug to a Class C3. This would enable pseudoephedrine medicines for the symptoms of cold and flu to be sold in pharmacies without a prescription.
Advising agencies:	Ministry of Health | Manatū Hauora
Proposing Ministers:	Hon David Seymour, Associate Minister of Health
Date finalised:	*12 January 2024*

Problem Definition

Patients are unable to access over the counter medicines containing pseudoephedrine medicines for the self-treatment of cold symptoms in New Zealand. Pseudoephedrine is an effective medicine for the treatment of rhinitis,[1] sinus and nasal congestion. The lack of access is the result of a ban on retail sales of these medicines enacted in 2011. This policy has not fulfilled its intention to decrease the supply of methamphetamine in New Zealand.

Executive Summary

In 2011, pseudoephedrine was scheduled as a Class B2 controlled drug under the Misuse of Drugs Act (MoDA) 1975, and a prescription medicine under the Medicines Regulations 1984. As a result, cold and flu medicines containing pseudoephedrine became unavailable for purchase without a prescription in New Zealand. Since this time, pharmaceutical companies have allowed their product approvals to lapse, which effectively means these products are unavailable in New Zealand.

In order to allow access to cold and flu medicines containing pseudoephedrine in New Zealand, there will need to be an amendment to the MoDA 1975, to either reclassify or remove pseudoephedrine as a controlled drug. In addition to the status quo, this Regulatory Impact Statement considers the following two mutually exclusive options:

- Reclassify pseudoephedrine under the MoDA 1975 from a Class B2 to a Class C3 (partially exempted) controlled drug. Pseudoephedrine's status as a precursor substance under the MoDA would remain. This is the Ministry of Health's preferred option.
- Remove pseudoephedrine as a controlled drug under the MoDA 1975. Pseudoephedrine would remain as a precursor substance under the Act.

[1] Rhinitis is inflammation and swelling of the mucous membrane of the nose, characterized by a runny nose, nasal congestion, stuffiness, sneezing and is usually caused by the common cold or a seasonal allergy.

When considering these options, the Ministry engaged with a number of stakeholders, including Health New Zealand, the New Zealand Police, the New Zealand Customs Service, the National Drug Intelligence Bureau (NDIB) and the Ministry of Justice. The views of key pharmacy representatives and clinicians were also sought.

Reclassifying pseudoephedrine as a Class C3 (partially exempted) controlled drug under the MoDA 1975 is the Ministry's preferred option, as it significantly increases access to cold and flu medicines containing pseudoephedrine whilst limiting the risks associated with this increase in access. Under this option, a licence will still be required to import and/or export products containing pseudoephedrine, so the New Zealand Customs Service will retain powers to seize illicit importations. There is unlikely to be an increase in the overall supply of methamphetamine in New Zealand, however domestic manufacture of the drug may increase.

In addition to changing pseudoephedrine's classification under the MoDA 1975, it will also be necessary to change the classification under the Medicines Regulations 1984. The most appropriate option is to reclassify pseudoephedrine as a restricted medicine.

Limitations and Constraints on Analysis

The Coalition Government's 100-day plan includes the commitment to "allow the sale of cold medication containing pseudoephedrine". This set the scope of the options.

The options for change discussed in this Regulatory Impact Statement are to either reclassify pseudoephedrine (from a Class B controlled drug to a Class C controlled drug) or remove the controlled drug status altogether. We have not undertaken formal consultation on these options. We have relied on written information and discussions with Health New Zealand, the New Zealand Police, the New Zealand Customs Service, the NDIB, the Ministry of Justice, Medsafe and representatives of the pharmacy sector to understand the potential impacts. We have reasonable confidence in the evidence base for our recommended option, although there are inherent uncertainties when considering any intervention affecting the unregulated market for recreational drugs.

The main limitation in the policy development process has been the inability (due to time constraints) to undertake wider consultation on the classification decision under the Medicines Regulations 1984 (i.e., the change from a prescription medicine to either a restricted [pharmacist-only] or a pharmacy-only medicine). Minimal consultation was undertaken. Wider consultation may have provided more detailed information on impacts and operational matters affecting the health sector, medicine supply chain, pharmacies and consumers. There will be opportunities to engage with the sector during the implementation and evaluation stages.

There is no section on the marginal costs and benefits in this Regulatory Impact Statement, since costs have not been quantified. Instead the narrative sections describes where the costs and benefits will fall.

Responsible Manager

Suzanne Townsend

Manager, Regulatory Policy

Strategy, Policy and Legislation

Ministry of Health *12 January 2024*	
Quality Assurance (completed by QA panel)	
Reviewing Agency:	
Panel Assessment & Comment:	N/A

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

What is pseudoephedrine?

1. Pseudoephedrine is an active ingredient contained in some medicines used to relive the symptoms of cold and influenza (flu). Administered orally, it works by stimulating nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow). This reduces the amount of fluid released from the vessels, resulting in less swelling and mucus secretion, and relieves the symptoms of nasal congestion arising from a cold, flu or allergy.
2. Pseudoephedrine can also be used as a precursor substance for the illicit manufacture of the Class A controlled drug methamphetamine.

Access to pseudoephedrine in New Zealand: Background and current state

3. Pseudoephedrine is not currently available for consumer purchase in New Zealand. While pseudoephedrine can be prescribed by a medical practitioner, there are no active product approvals for pseudoephedrine products in New Zealand, which effectively means these products are unavailable.
4. Prior to 2004, cold and flu medicines containing pseudoephedrine were available to purchase '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 1975. This was intended to increase control over the illicit supply and use of pseudoephedrine. Specifically, pseudoephedrine was scheduled as a Class C Part 3 (C3; partially exempted) controlled drug for cough/cold/flu and decongestant preparations, and Class C Part 5 (C5) for all other preparations. Partially exempted products can be sold without a prescription.
5. Access was further restricted in 2011, when pseudoephedrine was rescheduled as a Class B2 controlled drug under the MoDA 1975, and a prescription medicine under the Medicines Regulations 1984. These classifications means that pseudoephedrine is currently only available through a prescription from a registered medical practitioner.
6. Medical practitioners rarely prescribe pseudoephedrine, largely because people are unlikely to attend a medical consultation for cold and flu symptom management. As a result, manufacturers have allowed their product approvals to lapse. This means there are currently no approved pseudoephedrine products available in New Zealand.
7. If no action is taken, the supply of pseudoephedrine in New Zealand is unlikely to change due to the regulatory environment. Pharmaceutical companies are unlikely to apply for consent for distribution for pseudoephedrine products as practitioners are unlikely to change their prescribing behaviour.

Alternative nasal decongestant products

8. In terms of alternative orally-administered products for the treatment of nasal decongestion, products containing phenylephrine are readily accessible in New Zealand. However, current scientific data do not support that the recommended dosage of orally-administered phenylephrine is effective as a nasal decongestant.[2]

[2] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine

9. Alternative over the counter products for the treatment of nasal congestion available in New Zealand include nasal sprays containing the active ingredients oxymetazoline, xylometazoline and ipratropium bromide.

Access to pseudoephedrine in other jurisdictions

10. In some other countries, products containing pseudoephedrine are available to purchase in pharmacies with specific controls (refer to Table 1).
11. In some jurisdictions such as the Netherlands, pseudoephedrine is not approved as a medicine due to concerns about adverse cardiac side effects.

Table 1: Access to pseudoephedrine in other jurisdictions

Jurisdiction	Prescription required?	Conditions of sale without a prescription
Australia	• **No** for any product containing less than 800mg of pseudoephedrine and all solid dose products containing less than 720mg of pseudoephedrine. • **Yes** for any product containing a higher dose.	• A pharmacist must be directly involved in the transaction. • Medicines must be kept behind the counter, away from public access/self-selection. • If the identity of the purchaser is unknown, an acceptable form of identification must be provided. • Electronic recording of transactions is mandatory in most states and voluntary in others.
Canada	• **No**	• Products whose only active ingredient is pseudoephedrine must be kept behind the counter. • Products containing pseudoephedrine with other active ingredients may be displayed on publicly accessible shelves in a pharmacy but may only be sold when a pharmacist is present.[a]
UK	• **No** for any product that contains less than 720mg pseudoephedrine or 180mg ephedrine. • **Yes** for any product containing a higher dose.	• Can be purchased over the counter under the supervision of a pharmacist.
US	• **No**	• Can be sold from locked cabinets or behind the counter. • There is a limit on the amount that can be purchased in a single day and each month. • Consumers must show photo ID and sign a written or electronic logbook (except for any purchase of a single sales package containing up to 60mg of pseudoephedrine). • Retailers must keep personal information about these customers for at least two years after the purchase of these medicines. • Some state governments mandate the use of electronic tracking systems.

[a] Noting that in New Zealand a pharmacy cannot open without the physical presence of a pharmacist.

Controlled drugs

12. Controlled drugs are identified in the MoDA 1975 and classified based on the risk of harm the drug poses to individuals, or to society, by its misuse. Schedule 1 (Class A), Schedule 2 (Class B) and Schedule 3 (Class C) controlled drugs pose a very high risk, high risk and moderate risk of harm, respectively. These schedules generally mirror lists of substances in the United Nations (UN) Single Convention on Narcotic Drugs (1961) and the UN Convention on Psychotropic Substances (1971).
13. Activities involving controlled drugs, including possession, prescribing, supply and administration, are more tightly controlled than for other medicines. In particular, the importing and exporting of controlled drugs requires an import or export licence to be issued prior to the shipment of drugs entering or leaving New Zealand.
14. Pseudoephedrine is currently classified as a Schedule 2 Part 2 (Class B2) controlled drug under the MoDA 1975. It is not included in the UN controlled drug lists.
15. As a controlled drug, a licence is required to import and/or export. Each consignment of drug imported into New Zealand requires a new 'Licence to Import Controlled Drugs'. An appropriate authorisation, for example a 'Licence to Deal in Controlled Drugs' or a 'Licence to Possess Controlled Drugs', is also required before the issuance of licences to import and/or export. Individual travellers may also carry into New Zealand limited quantities of a controlled drug that has been lawfully supplied to them overseas, for their personal use.

Precursor substances

16. The MoDA 1975 also includes Schedule 4, for precursor substances, which can be used in the manufacture of controlled drugs. Under sections 12A and 12AB of the MoDA 1975, it is illegal to supply, produce or manufacture any precursor substance, or import or export precursor substances for unlawful use (e.g., the production or manufacture of a controlled drug).
17. Schedule 4 generally mirrors the precursors listed in the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988). Part 3 of Schedule 4 contains the substances ephedrine and pseudoephedrine, which are listed in Table I of the UN Convention; this allows for additional Police powers in relation to these substances. Under this classification, warrantless search and surveillance can be carried out in specified circumstances (sections 20 to 22, and 48 of the Search and Surveillance Act 2012).

Methamphetamine supply and use in New Zealand

18. Pseudoephedrine can be used as a precursor substance for the illicit manufacture of the Class A controlled drug methamphetamine.
19. Methamphetamine is a Class A controlled drug under the MoDA 1975 and is the second most harmful drug in New Zealand, after alcohol. Of the illicit drugs, methamphetamine is estimated as having the highest social harm cost per kilogram ($1,108,361.71 per kilogram methamphetamine).[3]
20. Methamphetamine remains the most widely detected illicit drug in wastewater testing, which covers around 75% of New Zealand's population. Rural towns in Northland, Bay of Plenty, and Hawkes Bay have the highest rates of methamphetamine consumption.

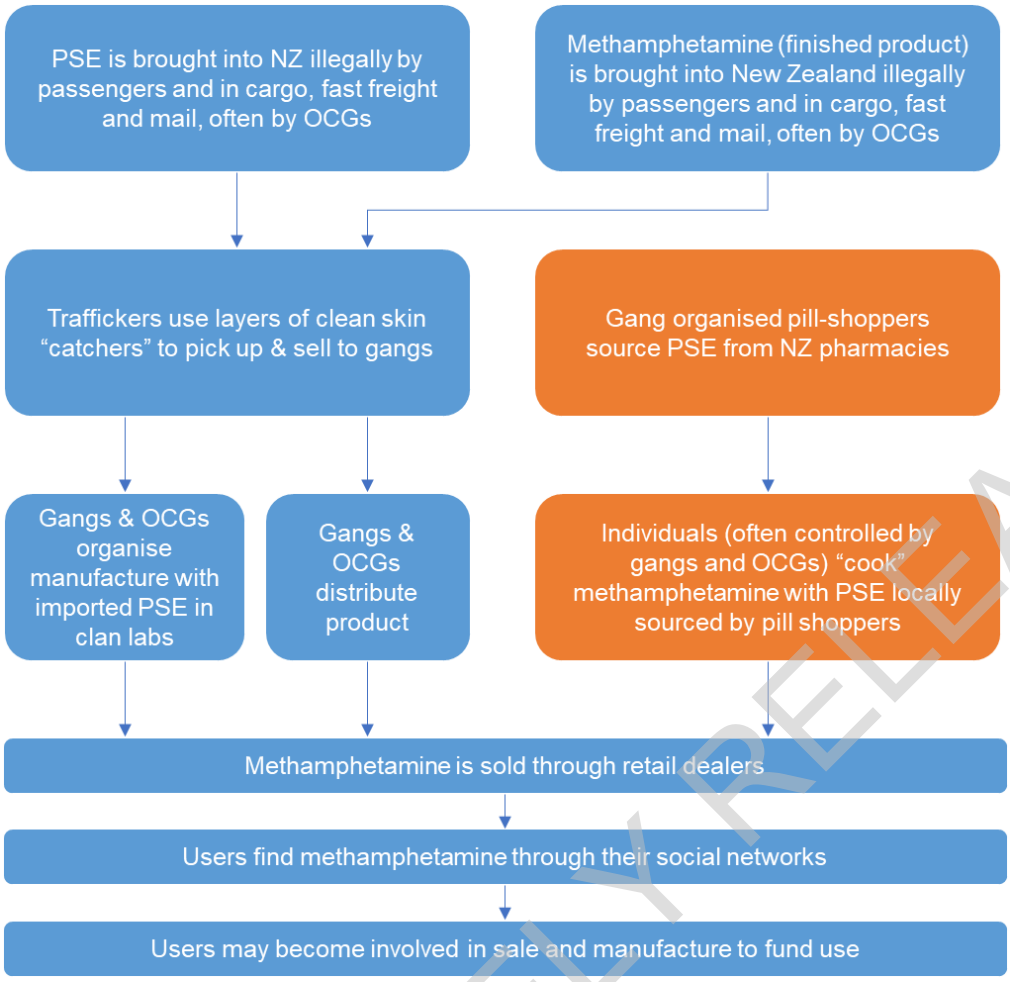
[3] McFadden M, Bellamore L & MacDonald B. 2022. The New Zealand Illicit Drug Harm Index 2020: Version 1.1. Wellington: Ministry of Health.

21. The 2021/2022 Health Survey found that people who use amphetamines (including methamphetamine) were 1.61 times more likely to be male than not, 1.99 times more likely to be Māori, 1.42 times more likely to be Pacific, 3.52 times more likely to have a disability, and 2.81 times more likely to live in the most deprived areas.
22. Māori are significantly and disproportionately impacted by methamphetamine use and consequent harms. Community leaders have highlighted the negative impacts from high rates of methamphetamine use as one of the most significant issues facing Māori.[4]
23. The social and economic impacts of methamphetamine use in New Zealand are significant. As well as causing significant harm to individuals' health, continued use of methamphetamine is associated with difficulty in sustaining jobs, risky sexual behaviour, breakup of significant relationships, children being taken into others' care, neonatal and infant adverse outcomes, 'feeling down' due to use, and involvement in crimes both under the influence of methamphetamine, or to sustain use.[5]
24. Large profit margins have led to the development of highly sophisticated distribution networks, including international organised crime groups (OCGs) and associated violence and harms. Figure 1 illustrates the methamphetamine supply chain and the involvement of OCGs.

[4] Yasbek P, Mercier K, Elder H, Crossin R, Baker M. 2022. Minimising the Harms from Methamphetamine. The Helen Clark Foundation and New Zealand Drug Foundation, Wellington.

[5] Evidence Based Policing Centre. 2021. Methamphetamine in New Zealand: What is currently known about the harm it causes? Wellington: NZ Police.

Figure 1: Methamphetamine supply chain



OCG: organised crime group; PSE: pseudoephedrine. Activities in orange boxes dormant since 2011. Modified from the DPMC methamphetamine – indicators and progress reports.

25. Currently, a significant proportion of the methamphetamine market in New Zealand is supplied by imported finished product. The volume of methamphetamine being imported into New Zealand has generally increased since 2012. Two large methamphetamine manufacturing regions, Mexico and the Golden Triangle, supply methamphetamine to the New Zealand market.[4]
26. Methamphetamine supply is supplemented by domestic manufacture in clandestine laboratories (clan labs) using imported precursors. According to NDIB advice, methamphetamine manufacturing laboratories are now almost exclusively commercial operations run by OCGs due to the prohibitive cost of purchasing precursor substances. Domestic OCGs dominate both the production and distribution of methamphetamine in New Zealand.[4]
27. Since 2011, the number of clan lab cases in New Zealand has generally decreased. In 2022, 62 clan labs were detected in New Zealand, 90% of which manufactured methamphetamine. Clan lab detections are impacted by law enforcement capacity and priorities.
28. Imported ephedrine and pseudoephedrine are both used in the illegal manufacture of methamphetamine. According to NDIB advice, while seizures of ephedrine have declined over the past five years, seizures of pseudoephedrine have increased. In 2022, pseudoephedrine overtook ephedrine as the most seized primary precursor. Furthermore, in 2022 a substantial supply line of pseudoephedrine from India was

identified. The quantities of pseudoephedrine identified suggest there may be substantial domestic manufacture of methamphetamine occurring in New Zealand.

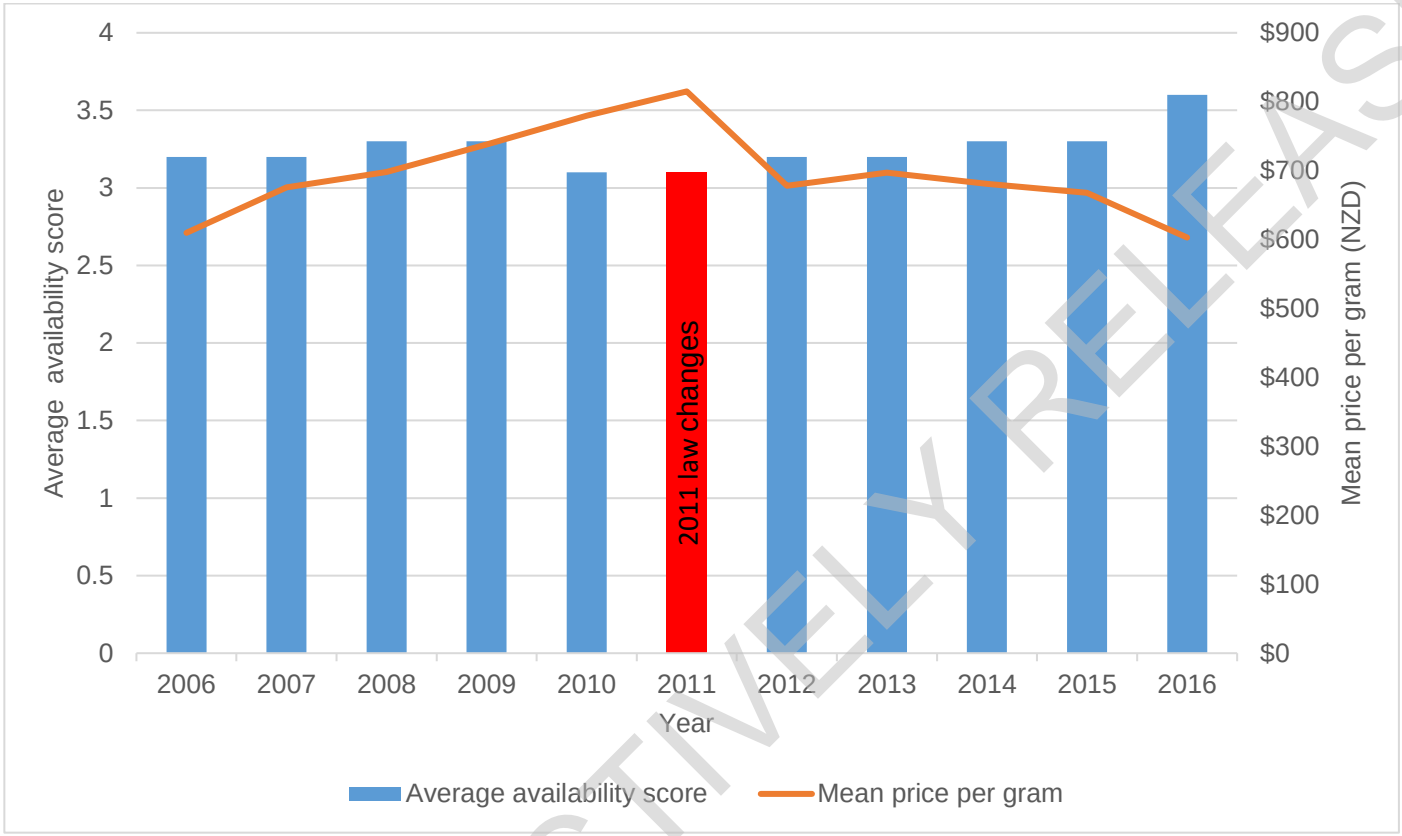
29. Home-based manufacture of methamphetamine is associated with risks from use of hazardous (caustic and corrosive) chemicals and solvents. Children living in settings of methamphetamine labs are at extremely high risk of a wide range of serious negative consequences including poisoning, homicides, and accidental deaths and burns due to home-based methamphetamine lab fires and explosions.[6] An average of 30 children were found in methamphetamine manufacturing laboratories every year between 2013 and 2015.[4]
30. Prior to the 2011 changes, pill-shopping from pharmacies was used to source pseudoephedrine for the manufacture of methamphetamine. In 2009 it was estimated that at least 10% of methamphetamine in New Zealand was derived from domestically diverted pseudoephedrine.[7]
31. The removal of this supply source had a limited impact on the price and availability of methamphetamine in subsequent years. Figure 2 shows the current availability and price of methamphetamine as reported by frequent drug-users. In the years following 2011, the average availability score generally increased, and the price per gram generally decreased. This indicates that suppliers adapted to use other supply routes (i.e., importing more methamphetamine and precursors).[8]

[6] Messina N, Jeter K, Marinelli-Casey P, West K, Rawson R. Children exposed to methamphetamine use and manufacture. Child Abuse Negl. 2014 Nov;38(11):1872-83.

[7] Gluckman P. 2009. Consideration of reduction of access to, or elimination of, pseudoephedrine in 'cold and flu' preparations – Report to the Prime Minister. Office of the Prime Minister's Science Advisory Committee.

[8] Wilkins C, Prasad J, Romeo JS, Rychert M. 2017. Recent trends in illegal drug use in New Zealand, 2006–2016: Findings from the Illicit Drug Monitoring System (IDMS). Auckland: Social and Health Outcomes Research and Evaluation (SHORE), College of Health, Massey University.

Figure 2: Availability and price of methamphetamine by combined frequent drug users, 2006–2016



Data are from Illicit Drug Monitoring System (IDMS) Report 2006–2016. Availability score is measured on a four-point type Likert scale varying from 'very difficult' (1) to 'very easy' (4).

What is the policy problem or opportunity?

Policy problem

32. New Zealanders are unable to access over the counter medicines containing pseudoephedrine for the self-treatment of cold symptoms. Pseudoephedrine is an effective medicine for the treatment of rhinitis, sinus and nasal congestion. The lack of access is the result of a ban on retail sales of these medicines enacted in 2011. This policy has not fulfilled its intention to decrease the supply of methamphetamine in New Zealand
33. The rationale for restricting access to pseudoephedrine was that, combined with intensified border enforcement, it would make it harder for criminals to source the key active ingredients to manufacture methamphetamine. It was thought this would result in increased prices and reduced availability of methamphetamine, and this in turn would lead to a reduction in associated drug harms such as addiction and organised crime.
34. However, the impact of the ban on retail sales of pseudoephedrine on the methamphetamine market was limited and temporary. Due to the high demand and ongoing high profit margins for methamphetamine in New Zealand, suppliers adapted to the law change by importing more methamphetamine as a finished product.
35. There is a case to modify the regulatory environment to encourage pharmaceutical companies to bring pseudoephedrine products to the New Zealand market, while limiting any increase in the domestic manufacture of methamphetamine.

What objectives are sought in relation to the policy problem?

36. There are four objectives sought in relation to the policy problem:
    a. **Objective 1:** New Zealanders have greater access to high-quality pseudoephedrine products for treating cold and flu symptoms;
    b. **Objective 2:** There remain the necessary controls over the illicit use of pseudoephedrine in the manufacture of methamphetamine;
    c. **Objective 3:** The risk of inappropriate therapeutic use of pseudoephedrine products is appropriately managed, and;
    d. **Objective 4:** Any impacts onto to the wider New Zealand health system (e.g., an increase in pharmacist workload) are minimised.
37. It will be necessary to ensure that pseudoephedrine products for treating cold and flu symptoms are accessible for New Zealanders (objective 1) whilst retaining the appropriate mechanisms to control for illicit use (objective 2).
38. Greater access to pseudoephedrine products (objective 1) increases the risk of inappropriate therapeutic use associated with these products. It will be important that these risks are managed (objective 3) whilst limiting the pressures this puts on the health system, including the health workforce (objective 4).

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

39. **Accessibility**: New Zealanders should have greater access to high-quality pseudoephedrine products for treating cold and flu symptoms.
40. **Border controls for illicit use**: There should be the necessary mechanisms to control for pseudoephedrine's illicit use as a precursor substance in the manufacture of methamphetamine. These mechanisms include the powers required by the New Zealand Customs Service and New Zealand Police to seize illicit importations of pseudoephedrine.
41. **Health risks for consumers**: The option should minimise the risk of inappropriate therapeutic use of pseudoephedrine products, in particular for patients who should not take it as it could cause serious side effects.
42. **Safety risks to pharmacists**: The option should minimise risks to pharmacists' safety (e.g., risk that pharmacies become the target of break-ins, thefts, ram raids, etc.).
43. **Health system pressures**: The New Zealand health system, including the practitioners (pharmacists) working in it, should not be unreasonably burdened.
44. **Harms associated with the domestic manufacture of methamphetamine**: The option should not exacerbate the harms associated with the manufacture of methamphetamine in New Zealand.

What scope will options be considered within?

45. There are no non-regulatory options that could achieve the objective in the Government's Coalition Agreement.
46. All feasible options that would make pseudoephedrine available for consumer purchase in New Zealand were considered. The scope includes all the regulatory powers available to the Minister of Health and Medsafe that may be needed to implement the proposal. This includes requirements for medicines (e.g., labelling, packaging, storage and stocktaking) which may be made under the MoDA 1975 and/or the Medicines Act 1981.

Consultation

47. To inform this analysis we discussed the policy problem and options with Health New Zealand, New Zealand Police, the National Drug Intelligence Bureau, Ministry of Justice, and the New Zealand Customs Service.
48. In addition, we held a focus group with key pharmacy representatives, including the Pharmaceutical Society of New Zealand, the Pharmacy Guild, Green Cross Health, Countdown Pharmacy, and Chemist Warehouse.
49. We also sought the views of clinicians through the Ministry of Health's Office of the Chief Clinical Officers, the College of General Practitioners, the General Practitioners' Sector Leader Group, and members of the Medicines Classification Committee.

What options are being considered?

50. There are three mutually exclusive options being considered:

- **Option One (status quo):** No reclassification of pseudoephedrine as a controlled drug. Pseudoephedrine remains a Class B2 controlled drug under the MoDA 1975.
- **Option Two (reclassify as Class C3):** Pseudoephedrine is reclassified from a Class B2 to a Class C3 (partially exempted) controlled drug under the MoDA 1975.

- **Option Three (remove controlled drug status):** Pseudoephedrine is removed as a controlled drug under the MoDA 1975.

Option One – Status quo

51. Under the status quo, pseudoephedrine would remain unavailable for consumer purchase in New Zealand. Pseudoephedrine would remain as a Class B2 controlled drug and a precursor substance under the MoDA 1975 (and a prescription medicine under the Medicines Regulations 1984). Due to the classification, pharmaceutical companies are unlikely to apply for consent for distribution as there is no financial incentive to do so.
52. Due to the controlled drug status, importations of pseudoephedrine that are identified as lacking appropriate licences can be seized by the New Zealand Customs Service.
53. Based on advice received from the NDIB, under the status quo, the methamphetamine market will continue to be supplied primarily by imported finished product, supplemented by domestic manufacture in clan labs using imported precursors.
54. Under the status quo, there is a likelihood that the New Zealand methamphetamine market will continue to expand, as transnational OCGs use increasingly sophisticated and diversified methods of production and trafficking.[9]

Option Two – Reclassify as Class C3

55. Under this option, pseudoephedrine products will become available for consumer purchase in New Zealand pharmacies.
56. Pseudoephedrine would be reclassified as a Class C controlled drug under the MoDA 1975, while remaining as a precursor substance. In order to be sold in community pharmacies, cold and flu medicines containing pseudoephedrine would need to be classified as partially exempted (Class C3).
57. To enable sale without a prescription, pseudoephedrine would also need to be reclassified under the Medicines Regulations 1984 (as restricted medicine or pharmacy-only medicine).
58. Due to the reclassification and subsequent increase in the market, pharmaceutical companies will likely make applications to Medsafe for consent for distribution for pseudoephedrine products. If and when products are approved by Medsafe, they will become available for consumer purchase.
59. This option would retain the powers afforded to the New Zealand Customs Service to seize unlicensed shipments of pseudoephedrine.

Health risks to consumers

60. With the increased availability of pseudoephedrine products, there is a risk of inappropriate therapeutic use. This risk can be mitigated with appropriate labelling requirements and/or classifying products as restricted (pharmacist-only) medicines (i.e., requiring consumers to speak with a pharmacist in order to purchase products).
61. As with all medicines, there is a risk of substandard, contaminated, and falsified products, which may harm consumers' health. This risk can be mitigated by ensuring a rigorous approval process with regulatory safeguards for all products entering into the New Zealand market.

[9] https://www.unodc.org/res/WDR-2023/WDR23_B3_CH1_Synthetic_drugs.pdf

Safety risks to pharmacists

62. With pseudoephedrine being stocked in pharmacies, there is an increased risk to pharmacists of ram raids and aggravated robberies by people involved in the manufacture of methamphetamine. Pharmacy representatives have emphasised that these incidents and associated anxiety can significantly affect the health and wellbeing of pharmacists.
63. The size of this risk is difficult to predict as it will depend on the wider New Zealand methamphetamine market (e.g., ease and cost of importing methamphetamine and precursors).
64. Risks may be mitigated to some extent with appropriate security measures. Some small pharmacies that have been the victim of an aggravated robbery or ram raid may be eligible for support from New Zealand Police's Retail Crime Prevention Programme. This can include the installation of measures such as fog cannons, bollards (in the case of ram raids), alarms and CCTV, tailored to the specific pharmacy's needs. The Ministry of Business, Innovation and Employment separately administer the Fog Cannon Subsidy Scheme. The Scheme subsidises up to $4,000 of the costs of the installation of a fog cannon for small retailers who meet eligibility criteria (retailers do not need to be a victim of retail crime).

Health system pressures

65. Under this option, there will be additional work for pharmacists to supply pseudoephedrine products. Workload will depend on the decision on classification under the Medicines Regulations 1984 (as a restricted or pharmacy-only medicine).
66. If made a restricted medicine, patients must consult with a pharmacist to purchase products containing pseudoephedrine, which would create additional work for pharmacists. Despite increased workload, pharmacist representatives generally support the classification as a restricted medicine to prevent inappropriate therapeutic use and to control diversion.

Domestic manufacture of methamphetamine

67. Under this option, a new supply line of pseudoephedrine will become available for the manufacture of methamphetamine. The NDIB advises that with increased domestic access, there is a risk that some pre-existing and new methamphetamine manufacturers will look to obtain pseudoephedrine from domestic sources (e.g., pharmacies). As a result, domestic manufacture of methamphetamine may increase, however not to the scale of production that was observed before the 2011 restrictions. Any shift in production location is unlikely to impact overall levels of methamphetamine demand and supply, assuming enforcement actions continue.
68. The NDIB predicts that the increase in domestic production will be primarily by individuals for smaller quantities of supply or for personal use. Currently, methamphetamine laboratories are almost exclusively commercial operations run by OCGs due to the prohibitive cost of purchasing precursor substances. With greater accessibility of pseudoephedrine in pharmacies, individuals will be able to manufacture methamphetamine on a smaller scale, without needing to establish connections with overseas suppliers of precursors. Existing supply routes for importing methamphetamine and precursors are likely to continue to operate at a similar level.
69. Under this option, it is likely that there will also be a corresponding increase in the sourcing and extraction of other precursor substances used in the manufacture of methamphetamine (e.g., iodine from tincture and red phosphorous from matchbox striking surfaces).

70. An increase in the number of domestic methamphetamine clan labs is likely to result in a corresponding increase in the number of laboratory fires. This is due to the extensive use of highly flammable solvents in the process of extracting pseudoephedrine from cold medicines.
71. An increase in the number of domestic methamphetamine labs will lead to greater risks for frontline Police staff who attend these addresses. The volatile flammable atmosphere that results from pseudoephedrine extraction can easily ignite into flash fires and make the environment unbreathable.
72. There is also the possibility that OCGs will establish syndicates of pill shoppers to obtain pseudoephedrine from pharmacies in larger quantities, to produce methamphetamine for supply. New Zealand does not have an electronic monitoring system that could be used to track purchases across pharmacies, in order to identify pill shopping.
73. Under this option, it would be challenging for Police to resource the monitoring, checking, and profiling of any pill shoppers. Police resources would focus on individuals where there is suspicion that pseudoephedrine is being obtained for illicit use, and where there is an impact on retail crime (e.g., from burglaries and ram raids).
74. During 2023, NDIB observed an increase in the number of pseudoephedrine tablets seized. This may indicate that crime groups are exploring methods of manufacturing methamphetamine with tablets that will become more accessible under this option.

Option Three – Remove controlled drug status

75. Similar to option two, under this option, pseudoephedrine products will become available for consumer purchase in New Zealand pharmacies. Consumers will also be able to order products online.
76. Pseudoephedrine would be removed from the controlled drug schedules under the MoDA 1975, while remaining as a precursor substance. This would enable products to be sold in community pharmacies.
77. To enable sale without a prescription, pseudoephedrine would also need to be reclassified under the Medicines Regulations 1984 (as restricted or pharmacy-only).
78. Pharmaceutical companies will likely make applications to Medsafe for consent for distribution for pseudoephedrine products. If and when products are approved by Medsafe, they will become available for consumer purchase.

Border controls for illicit use

79. Under this option, as pseudoephedrine would not be a controlled drug, a licence would no longer be required to import and/or export pseudoephedrine. The Customs Service has indicated that this option will make it harder for them to intercept illicit importations of pseudoephedrine at the border and would likely result in more pseudoephedrine entering New Zealand illegally.
80. Due to the remaining precursor status, the Customs Service would be able to seize illicit importations of pseudoephedrine if they had reasonable evidence that the substance was to be used unlawfully.

Additional health risks for consumers

81. Under this option, as a licence is not required to import and/or export, it will be easier for consumers to purchase pseudoephedrine online from overseas suppliers.
82. Online purchasing does not provide for clinical oversight so may lead to inappropriate therapeutic use.
83. In addition, there is a greater risk of substandard, contaminated and falsified products purchased online. Products purchased online may be different to those with regulatory

approval in New Zealand. Monitoring of overseas markets has shown an increase in the number of fraudulent webstores and the availability of counterfeit medicines. This creates a safety risk to consumers from accessing lower quality products.

Methamphetamine manufacture and supply

84. Similar to option two, a new supply line of pseudoephedrine will open up for the manufacture of methamphetamine. Smaller scale domestic manufacture is likely to increase with associated health and safety harms as per option two.
85. As borders will be more permeable to imports of pseudoephedrine for unlawful use, domestic manufacture may increase further, depending on the global synthetic drugs market.
86. With more permeable borders, illegal importation of precursor substances for the domestic manufacture of methamphetamine will continue and may increase. If manufacturers become dependent on this supply line and there is a supply shock (e.g., disruption of an international distribution network), they may turn to pharmacies to maintain supply.
87. Overall this option is associated with a higher degree of risk and uncertainty in relation to the illicit market, compared to option two.

How do the options compare to the status quo/counterfactual?

Key:

++	much better than status quo	0	about the same as the status quo	-	worse than the status quo
+	better than the status quo			- -	much worse than the status quo

	Option One – *Status quo*	Option Two – *Reclassify as Class C3*	Option Three – *Remove controlled drug status*
Accessibility	**0** Under the status quo, cold and flu medicines containing pseudoephedrine would remain unavailable for consumer purchase without prescription, with no products holding approvals in New Zealand.	**+ +** Due to the reclassification, pharmaceutical companies will likely make applications to Medsafe for consent for distribution. If and when products are approved, cold and flu medicines containing pseudoephedrine will become available for consumer purchase.	**+ +** Similar to option two, cold and flu medicines containing pseudoephedrine will become likely available for consumer purchase following applications from pharmaceutical companies to Medsafe for consent for distribution. Consumers will also be able to order products online.
Border controls for illicit use	**0** Border controls will remain. Import and export licensing is required, and shipments of unlicensed imports can be seized.	**0** The outcome will be similar to the status quo. Import and export licensing is required, and shipments of unlicensed imports can be seized.	**-** As pseudoephedrine is not a controlled drug, the powers afforded to the New Zealand Customs Service to seize shipments would be reduced, meaning more illegal shipments of pseudoephedrine will enter New Zealand.
Health risks for consumers	**0** As medicines containing pseudoephedrine are unavailable for consumer purchase in New Zealand, the absolute risk of inappropriate therapeutic use is very low. There is a low risk to consumers from self-administering products purchased from other countries without appropriate clinical oversight.	**-** There is a risk of inappropriate therapeutic use. This risk can be mitigated with appropriate labelling requirements and/or classifying products as restricted medicines (i.e., requiring consumers to consult with a pharmacist to purchase).	**- -** As per option two, there is a risk of harm from inappropriate therapeutic use which can be mitigated with appropriate labelling and/or pharmacist consultation. There is an additional risk from products ordered online being taken without appropriate clinical oversight or being lower in quality than products with regulatory approval in New Zealand.

Safety risks to pharmacists	**0** Pharmacists do not currently dispense pseudoephedrine-containing products in New Zealand, so there is no associated security risk.	**-** With pseudoephedrine being stocked in pharmacies, there is an increased risk to pharmacists of ram raids and aggravated robbery by people involved in the manufacture of methamphetamine.	**-** Similar to option two, there is an increased risk to pharmacists of aggravated behaviour by people involved in the manufacture of methamphetamine.
Health system pressures	**0** Medical practitioners do not currently prescribe or supply pseudoephedrine- containing products, so there are no health system pressures.	**-** There may be an additional workload for pharmacists to supply pseudoephedrine products. Workload will depend on the decision on classification under the Medicines Regulations 1984 (e.g., patient consultation and recording details of sales).	**-** As per option two, there may be additional workload for pharmacists to supply products, determined by the Medicines Regulations 1984 classification.
Harms associated with the domestic manufacture of methamphetamine	**0** Domestic manufacture of methamphetamine by commercial clan labs occurs on a small scale, with associated health and environmental harms.	**-** With increased access through community pharmacies, it is likely that domestically sourced pseudoephedrine will be used to manufacture methamphetamine, in addition to imported precursors. The scale of domestic manufacture may increase with associated health and safety harms from occupational exposure to manufacturing process.	**-** Similar to option two, it is likely that domestically sourced pseudoephedrine will be used to manufacture methamphetamine, which may increase overall domestic manufacture and associated health and safety harms.
Overall assessment	**0** Under the status quo, New Zealanders would remain unable to purchase cold and flu medicines containing pseudoephedrine without a prescription. Consequently, the health risks for consumers are low, and there are no safety risks to pharmacists. The NZ Customs Service would retain the necessary border controls for the illicit use of pseudoephedrine. Domestically manufactured methamphetamine is likely to remain a small proportion of the overall supply in New Zealand.	**+** This option would achieve the primary objective of increasing accessibility. New Zealanders would be able to purchase cold and flu medicines containing pseudoephedrine without a prescription. There are some health risks for consumers and safety risks to pharmacists associated with the increase in accessibility. The NZ Customs Service would retain the appropriate controls to seize unlicensed shipments of pseudoephedrine. There is likely to	**-** This option would achieve the primary objective of increasing accessibility. Cold and flu medicines containing pseudoephedrine would become available for purchase without a prescription. Unlike option two, however, the NZ Customs Service would not retain the necessary border controls. Reducing border controls to this extent would introduce a level of risk in relation to the illicit market. It would also make it easier to purchase lower quality pseudoephedrine

		be an increase in local manufacture of methamphetamine, using pseudoephedrine sourced domestically from pharmacies.	medicines online, which is an additional health risk for consumers.

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Option two is the preferred approach

88. Reclassifying pseudoephedrine under the MoDA 1975 from Class B2 to Class C3 is the preferred approach as it achieves the primary objective of increasing accessibility, while minimising diversion and the risks of inappropriate therapeutic use as much as possible.
89. By leaving pseudoephedrine as a controlled drug, a licence will still be required to import and/or export. The New Zealand Customs Service will retain powers to seize unlicensed shipments, meaning that less pseudoephedrine will be imported for unlawful use, compared to option three.
90. Under this option, consumers will only be able to buy approved products in pharmacies. If pseudoephedrine is classified as a restricted medicine under the Medicines Regulations 1984, this will provide the opportunity for pharmacists to give appropriate clinical advice and oversight.
91. The impacts on the domestic manufacture of methamphetamine and subsequent risks to pharmacists are highly difficult to predict, however impacts will likely be similar between options two and three. Domestic manufacture of methamphetamine may increase, however any shift in production location is unlikely to impact overall levels of methamphetamine demand and supply, assuming enforcement actions continue.
92. With both options two and three, there is a risk that products are used by patients with contraindications and precautions without appropriate clinical oversight. Health risks to consumers may be reduced with appropriate labelling and/or classifying products as restricted. If made restricted medicines, pharmacists would have a greater ability to monitor purchasing and address any risks to individual consumers. The risk to consumers' health is lower with option two compared to option three as consumers will not be able to order unapproved products online.

Section 3: Delivering an option

How will the new arrangements be implemented?

93. The preferred option would be given effect via a Misuse of Drugs Amendment Bill which will change the classification of pseudoephedrine as a controlled drug.
94. A Misuse of Drugs Amendment Bill alone will not enable cold and flu medicines containing pseudoephedrine to be sold in New Zealand pharmacies without a prescription. The classification of pseudoephedrine under the Medicines Regulations 1984 will also need to be changed from a prescription-only medicine.
95. There are three options for the classification of pseudoephedrine under the Medicines Regulations 1984: restricted (pharmacist-only), pharmacy-only, and general sale. The most appropriate option is to classify pseudoephedrine as a restricted medicine.
96. Restricted medicines may be sold without a prescription, but the sale must be made by a registered pharmacist in a pharmacy, and the details of the sale must be recorded.
97. Classifying pseudoephedrine as a restricted medicine is aligned with regulatory settings in other jurisdictions. This classification is also supported by the stakeholders we consulted with.
98. If made a restricted medicine, patients must consult with a pharmacist to purchase products containing pseudoephedrine. Although this classification will increase the workload of pharmacists, representatives we spoke to were generally supportive of this option as it provides greater clinical oversight and may help to control diversion.
99. Additionally, any pseudoephedrine products will need to be approved by Medsafe, the authority responsible for the regulation of therapeutic products, before they can be sold in New Zealand. This approval process is initiated by manufacturers and will likely occur following confirmation of the new regulatory settings. The Ministry of Health will draft communications materials that publicly announce these settings.
100. We have received advice that the lead time can be significant before companies are able to supply products to New Zealand, and that this could take up to 12 months.
101. It should be noted that the new arrangements will not require pharmacies to sell cold medicines containing pseudoephedrine. It will be up to pharmacy businesses to decide whether or not to sell these products.
102. Working with the appropriate agencies (e.g., New Zealand Customs Service, New Zealand Police, Medsafe, etc.), responsible authorities, and professional bodies, the Ministry of Health will develop a communications plan that provides impacted stakeholders (e.g., pharmacists, consumers, etc.) with information on the changes being implemented.
103. It is important that any communications address the matters raised by stakeholders during the consultation period. These include concerns raised by pharmacists that they will be targeted by people involved in the domestic manufacture of methamphetamine (e.g., ram raids, robberies, etc.).

Implementation risks

104. Possible implementation risks include the possibility that pharmaceutical companies will not apply for product approvals in New Zealand, potentially because the market is relatively small. This is unlikely as some companies have expressed interest in response to the Coalition Government's commitment. Companies may be discouraged from applying if there is uncertainty regarding the regulatory settings. To avoid this, regulatory processes and classification decisions will be publicly announced in a clear and transparent manner.
105. Another possible implementation risk is that pharmacists decide not to sell pseudoephedrine products due to safety concerns or other objections. We predict this

is unlikely as pseudoephedrine products are likely to be popular, however it will be necessary to address pharmacists' concerns with clear guidance and protective provisions as part of the implementation.

How will the new arrangements be monitored, evaluated, and reviewed?

106. Post-implementation assessments are expected for 100-day plan proposals. The primary expected outcome is that high quality medicines containing pseudoephedrine become available for purchase. This outcome depends largely on suppliers' willingness and ability to supply. Assuming this outcome occurs, we plan to assess the results one year after pseudoephedrine products become available, including looking at whether the identified risks have eventuated. We will prepare an evaluation plan in advance, adopting a multi-agency approach.