Te Kāwanatanga o Aotearoa
New Zealand Government

MANATŪ HAUORA
MINISTRY OF HEALTH

Associate Minister of Health (Pharmac)

Allowing sales of cold medicines containing pseudoephedrine

Date of publishing: 20 February 2024

These documents have been proactively released by the Ministry of Health on behalf of the Associate Minister of Health (Pharmac), Hon David Seymour.

Title of Cabinet papers:

- Allowing sales of cold medicines containing pseudoephedrine
- Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024: Approval for Introduction

Title of minutes:

- Report of the Cabinet 100-Day Plan Committee: Period Ended 19 January 2024 (CAB-24-MIN-0002)
- Allowing sales of cold medicines containing pseudoephedrine (100-24-MIN-0003)
- Report of the Cabinet Legislation Committee: Period Ended 16 February 2024 (CAB-24-MIN-0037)
- Misuse of Drugs (Pseudoephedrine) Amendment Bill and Medicines (Pseudoephedrine) Amendment Regulations (LEG-24-MIN-0002)

Some information has been redacted from the Cabinet minute as it is out of scope of this proactive release.

The associated regulatory impact statement is available here.

Cabinet

Minute of Decision

Report of the Cabinet 100-Day Plan Committee: Period Ended 19 January 2024

On 23 January 2024, Cabinet made the following decisions on the work of the Cabinet 100-Day Plan Committee for the period ended 19 January 2024:

Out of scope

100-24-MIN-0003	**Allowing Sales of Cold Medicines Containing Pseudoephedrine** Portfolio: Associate Health (Hon David Seymour)	CONFIRMED

Out of scope

Rachel Hayward
Secretary of the Cabinet

100-24-MIN-0003

Cabinet 100-Day Plan Committee

Minute of Decision

Allowing Sales of Cold Medicines Containing Pseudoephedrine

Portfolio **Associate Health (Hon David Seymour)**

On 17 January 2024, the Cabinet 100-Day Plan Committee:

1 **noted** that as part of Cabinet's 100-Day Plan, the Minister of Health has been asked to provide policy proposals to allow the sale of medicines for relieving the symptoms of the common cold containing pseudoephedrine ('pseudoephedrine products') [CAB-23-MIN-0468];

2 **noted** that, to allow the sale of pseudoephedrine products, an amendment to the Misuse of Drugs Act 1975 will be required;

3 **agreed** to amend the Misuse of Drugs Act 1975 (and associated regulations) to reclassify pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug;

4 **noted** that, to allow the sale of pseudoephedrine products without prescription, an amendment to the Medicines Regulations 1984 will be required;

5 **agreed** to amend the Medicines Regulations 1984 to reclassify pseudoephedrine, where it is contained in cold and flu medicines, from a prescription medicine to a restricted medicine;

6 **invited** the Associate Minister of Health (Hon David Seymour) (the Associate Minister) to issue drafting instructions to the Parliamentary Counsel Office to give effect to the decisions in paragraphs 3 and 5;

7 **noted** that a bid will be submitted for the 2024 Legislation Programme for a Misuse of Drugs Amendment Bill, with a category 3 priority (to be passed by the end of 2024);

8 **noted** that pseudoephedrine products will need to be approved as new medicines under the Medicines Act 1981, following evaluation of applications by pharmaceutical companies;

9 **noted** that the timeframe for the supply of pseudoephedrine products into New Zealand will depend on suppliers;

10 **noted** that the Associate Minister intends to make a public announcement in the days following Cabinet confirmation of the Committee's decisions.

Jenny Vickers
Committee Secretary

Attendance: (see over)

Present:
Rt Hon Christopher Luxon (Chair)
Rt Hon Winston Peters
Hon David Seymour
Hon Nicola Willis
Hon Chris Bishop
Hon Dr Shane Reti
Hon Brooke van Velden
Hon Shane Jones
Hon Simeon Brown
Hon Erica Stanford
Hon Paul Goldsmith
Hon Judith Collins

Officials present from:
Office of the Prime Minister
Department of the Prime Minister and Cabinet

In Confidence

Office of the Associate Minister of Health

Cabinet 100-Day Plan Committee

Allowing sales of cold medicines containing pseudoephedrine

Proposal

1 This paper seeks approval to amend the Misuse of Drugs Act 1975 and consequential amendments to regulations to allow for the sale of cold and flu medicines containing pseudoephedrine without a prescription.

Relation to government priorities

2 The Government's 100-day plan includes a commitment to "allow the sale of cold medication containing pseudoephedrine" [CAB-23-MIN-0468 refers].

3 This paper begins the process to fulfil this commitment by proposing amendments to the Misuse of Drugs Act 1975 and the Medicines Regulations 1984 to reclassify pseudoephedrine.

Executive Summary

4 In 2011, changes were made to more tightly regulate cold and flu medicines containing pseudoephedrine in an attempt to prevent these medicines from being diverted to the illicit manufacture of methamphetamine.

5 As a result of these changes suppliers have allowed any product approvals to lapse and pseudoephedrine cold and flu medicines are effectively unavailable in New Zealand.

6 These tighter controls on pseudoephedrine have had a minimal effect on the overall supply of methamphetamine in New Zealand as manufacturers and importers have moved on to other supply pathways.

7 Legislative changes are required to relax these controls to enable access to effective medicines that relieve the symptoms of cold and flu.

8 I propose the Misuse of Drugs Act 1975 (and associated regulations) be amended to reclassify pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug.

9 I propose the Medicines Regulations 1984 be amended to reclassify pseudoephedrine, where it is contained in cold and flu medicines, from a prescription medicine to a restricted medicine.

10 Legislation will be drafted and introduced by 8 March 2024 in accordance with the Government's commitment in the 100-day plan.

Background

11 Pseudoephedrine is a substance that is commonly used alone or in combination with other medicines to treat nasal congestion from a cold, flu or allergy.

12 Pseudoephedrine is also a precursor substance, used in the manufacture of the Class A drug methamphetamine.

In 2011, access to pseudoephedrine was restricted

13 Prior to 2011, the New Zealand public could purchase medicines containing pseudoephedrine from community pharmacies for the purpose of relieving cold and flu symptoms.

14 In 2011, as part of a plan to reduce the harms associated with methamphetamine use, the Government made medicines containing pseudoephedrine prescription-only under the Medicines Regulations 1984.

15 At the same time, pseudoephedrine was reclassified from a Class C3 controlled drug to Class B2 controlled drug under the Misuse of Drugs Act 1975. The aim of these changes was to limit the amount of pseudoephedrine being diverted from pharmacies for the manufacture of methamphetamine, and to increase penalties for offending.

The impact on illicit supply of methamphetamine has been limited

16 Since the 2011 classification changes, methamphetamine has become cheaper and more available. Suppliers adapted to the law change by focusing on importing methamphetamine as a finished product.

17 The trend of increased supply of methamphetamine is global, as trans-national organised crime groups use increasingly sophisticated and diversified methods of production and trafficking. In New Zealand in 2023, methamphetamine was mainly supplied by importations of finished product, facilitated by organised crime groups in Asia, the Americas, and the Middle East.

18 The supply of methamphetamine in New Zealand is supplemented by domestic manufacture of the drug using a range of precursor substances, including illicitly imported pseudoephedrine.

19 Ongoing high demand and profit margins for methamphetamine will continue to ensure New Zealand is a lucrative market, and as a result, suppliers will adapt to changes in the regulatory settings.

Restrictions have led to pseudoephedrine products being inaccessible

20 Due to its classification, only medical practitioners can currently prescribe products containing pseudoephedrine. Medical practitioners rarely prescribe pseudoephedrine products.

21 The high barriers to accessing pseudoephedrine products have led to low demand for these products. As a result, manufacturers have allowed their product approvals to lapse. There are currently no pseudoephedrine products approved or available in New Zealand.

22 By lifting these restrictions, the market for pseudoephedrine cold and flu medicines would return and suppliers are highly likely to reintroduce these products.

Proposed legislative changes

23 I propose that the Misuse of Drugs Act 1975 be amended to reclassify pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug.

24 I propose pseudoephedrine continue to be classified as a precursor substance under Schedule 4 of the Misuse of Drugs Act 1975. This means it will continue to be an offence to supply, produce or manufacture pseudoephedrine knowing it is to be used to commit an offence (e.g., the production or manufacture of a controlled drug). This is in line with the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

25 I also propose that the Medicines Regulations 1984 be amended to reclassify cold and flu products containing pseudoephedrine from prescription medicines to restricted medicines. Under this proposal any other types of products containing pseudoephedrine would remain prescription only.

Reclassifying pseudoephedrine under the Misuse of Drugs Act 1975

26 Reclassifying pseudoephedrine as a Class C3 (partially exempt) controlled drug will enable the supply of pseudoephedrine products without a prescription, while also retaining appropriate border controls.

27 Class C3 (partially exempt) controlled drugs are still subject to tight controls over their illicit supply, but they are exempted from many requirements that inhibit supply for therapeutic purposes. These exemptions are defined in the Misuse of Drugs Regulations 1977 and may need to be amended to ensure the policy intent is met. This will become clear through the drafting process.

28 Suppliers will still need a licence to import and export pseudoephedrine, and Customs can intercept shipments of unlicensed imports.

29 As a controlled drug, people can bring into New Zealand up to one month’s supply for their own use to treat a medical condition, providing the medicine was lawfully supplied overseas. It would not be lawful to import for personal use by mail, or by online shopping. This restriction would be appropriate to ensure that only safe, effective pseudoephedrine products are supplied in New Zealand.

30 Pseudoephedrine is included in the Misuse of Drugs Regulations 1977, so I also propose that any necessary amendments to those regulations as a consequence of reclassification are made in the Bill.

Reclassifying pseudoephedrine under the Medicines Regulations 1984

31 Medicines may be general sale or they may be classified under the Medicines Regulations 1984 as prescription, restricted, or pharmacy only. Pseudoephedrine is currently classified as a prescription medicine.

32 I propose that cold and flu products containing pseudoephedrine be reclassified from prescription medicines to restricted medicines. A restricted classification means customers making a purchase at a physical pharmacy will need to do so by way of a face-to-face transaction with a pharmacist. The pharmacist must record information, and can highlight advice as appropriate. Restricted classification also ensures pharmacists can counsel patients who should not take pseudoephedrine for clinical reasons.

33 This change will provide wider access to pseudoephedrine products while ensuring some protections remain to encourage appropriate use and reduce the likelihood of diversion.

34 Medicines containing pseudoephedrine for other therapeutic uses will be classified as appropriate, according to their risk. This change would be a return to the pre-2011 settings and is similar to the current settings in other jurisdictions, such as Australia.

Risks

35 Under this proposal, a new supply line of pseudoephedrine will open up which may result in an increase in the domestic manufacture of methamphetamine. Any shift in production location would not impact on overall levels of methamphetamine demand and supply. The NZ Customs Service and NZ Police will continue to take enforcement actions and monitor for any changes.

36 Pharmacists have expressed concerns that the proposed change would increase the risk of pharmacies being targeted by thieves, robberies and by people shopping for precursors.

37 Pharmacists have also noted that the change will impact on pharmacists' workload at a time where there is a shortage of pharmacists.

Additional changes will be required to enable supply of pseudoephedrine products

38 Prior to the 2011 changes, there were several approved pseudoephedrine products marketed in New Zealand. Following the 2011 reclassification, companies allowed their product approvals to lapse.

39 Products that have not been generally available for longer than five years are "new medicines" under the Medicines Act 1981. This means that to begin

selling pseudoephedrine products in New Zealand, pharmaceutical companies will need to submit a New Medicines Application to Medsafe, who may use an expedited provisional consent process, if appropriate, which would ensure timeliness while assuring product quality.

40 The New Medicines Application process is initiated by pharmaceutical companies and is dependent on their interest and ability to apply for consent and supply products in New Zealand. I am advised that some companies have expressed interest in response to the Coalition Government's commitment.

41 Once the pharmaceutical companies know what the requirements will be (if and when the proposed changes are adopted), they will be in a position to consider whether to seek approval and supply their products. I am advised 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.

Implementation and timing

42 A Bill to implement the proposal can be drafted and introduced within the government's first 100 days.

43 Regulations amending the Medicines Regulations 1984 will be drafted and will come into effect before enactment of the amendment.

44 The actual timeframe for pseudoephedrine products becoming available for purchase in New Zealand is dependent on the speed of pharmaceutical companies to supply the New Zealand market, including to provide the necessary information for product approval.

Cost-of-living Implications

45 There are no significant cost-of-living implications from this proposal. Over-the-counter medicines (such as restricted medicines) are not funded by the government, but pseudoephedrine products are unlikely to be expensive.

Financial Implications

46 There are no financial implications from this proposal.

Legislative Implications

47 Legislation is required to implement the proposal.

48 It is proposed that a Misuse of Drugs Amendment Bill to implement the proposal has a Category 3 priority – to be passed by the end of 2024. The Bill can be drafted and introduced within the Government's first 100 days.

49 Regulations amending the Medicines Regulations 1984 will be drafted and will come into effect before enactment of the amendment.

Impact Analysis

Regulatory Impact Statement

50 A Regulatory Impact Statement (RIS) has been completed and is attached as appendix one.

51 The requirement for quality assurance of RISs has been suspended for decisions relating to 100-Day Plan proposals taken within the 100 days. However, the Ministry of Health notes that the impact analysis has been limited by a lack of wide consultation with affected stakeholders.

Population Implications

52 There are no significant population impacts. The adverse impacts of any increased domestic manufacture of methamphetamine will likely be greater for populations living in more deprived areas.

53 Classifying pseudoephedrine as a restricted medicine will mean that is only available through a registered pharmacist. This requirement will be a barrier to people who have a higher difficulty accessing a pharmacist, such as those in rural areas.

Human Rights

54 The proposals in this paper are not inconsistent with the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Use of external resources

55 No contractors or consultants have been involved in developing this paper.

Consultation

56 The Ministry of Health advises it has conducted limited consultation with representatives of affected stakeholder groups. I am satisfied that this consultation will meet the statutory prerequisites under section 105 of the Medicines Act 1981 for consultation on amendments to Medicines Regulations.

57 The following agencies have been consulted on this paper: Health New Zealand | Te Whatu Ora, NZ Police, National Drug Intelligence Bureau, NZ Customs Service, Ministry of Justice and the Department of the Prime Minister and Cabinet.

Communications

58 I intend to make an announcement in the days following Cabinet confirmation of the Committee's decisions. This announcement will provide certainty to the potential suppliers of pseudoephedrine products on the intended regulatory settings.

Proactive Release

59 I intend to proactively release this paper in whole when the decision is announced. This Cabinet paper and RIS will be made available on the Ministry of Health and Treasury websites.

Recommendations

The Associate Minister of Health recommends that the Committee:

1 **note** that as part of Cabinet's 100-Day Plan the Minister of Health has been asked to provide policy proposals to allow the sale of medicines for relieving the symptoms of the common cold containing pseudoephedrine ('pseudoephedrine products') [CAB-23-MIN-0468];

2 **note** that to allow the sale of pseudoephedrine products, an amendment to the Misuse of Drugs Act 1975 will be required;

3 **agree** to amend the Misuse of Drugs Act 1975 (and associated regulations) to reclassify pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug;

4 **note** that to allow the sale of pseudoephedrine products without prescription, an amendment to the Medicines Regulations 1984 will be required;

5 **agree** to amend the Medicines Regulations 1984 to reclassify pseudoephedrine, where it is contained in cold and flu medicines, from a prescription medicine to a restricted medicine;

6 **authorise** the Associate Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendations 3 and 5;

7 **agree** that a Misuse of Drugs Amendment Bill to implement the proposal has a Category 3 priority – to be passed by the end of 2024;

8 **note** that pseudoephedrine products will need to be approved as new medicines under the Medicines Act 1981, following evaluation of applications by pharmaceutical companies;

9 **note** that the timeframe for supply of pseudoephedrine products into New Zealand will depend on suppliers;

10 **note** I intend making a public announcement in the days following Cabinet confirmation of the Committee's decisions.

Authorised for lodgement

Hon David Seymour

Associate Minister of Health