MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Allowing access to pseudoephedrine

Date due to MO:	15 December 2023	**Action required by:**	20 December 2023
Security level:	IN CONFIDENCE	**Health Report number:**	H2023033231
To:	Hon David Seymour, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
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Minister's office to complete:

☑ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☑ See Minister's Notes	☐ Withdrawn	

Comment:

Nice one.

Allowing access to pseudoephedrine

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To:	Hon David Seymour, Associate Minister of Health		

Purpose of report

1. This briefing sets out the options to allow the sale of pseudoephedrine-based cold medicines in New Zealand, and to confirm your agreement to the next steps of this work.

2. This report discloses all relevant information and implications.

Summary

3. The Coalition Government's 100-day plan includes an action to "allow the sale of cold medication containing pseudoephedrine". Cabinet has agreed that you will report back with policy options by the end of January 2024 [CAB-23-MIN-0468].

4. In 2011, pseudoephedrine became a Class B controlled drug under the Misuse of Drugs Act 1975 primarily due to its use in the domestic production of methamphetamine.

5. Due to its classification, a prescription is currently required to access products containing pseudoephedrine.

6. There are two regulatory changes required to allow access to pseudoephedrine products without a prescription:

   a. amend the Misuse of Drugs Act 1975, to either reclassify or remove pseudoephedrine as a controlled drug

   b. change pseudoephedrine's classification as a prescription medicine under the Medicines Regulations 1984.

7. The decision to reclassify or remove pseudoephedrine as a controlled drug has implications on the ability of Customs to control the illicit supply at the border.

8. Following these regulatory changes, any pseudoephedrine products will be subject to an approval process before they will become available for sale. Medsafe will initiate an expedited provisional consent process with suppliers.

9. However, early information from suppliers suggests that they will not be able to supply pseudoephedrine products to New Zealand for up to a year due to manufacturing lead times.

Recommendations

We recommend you:

a) **Note** that as part of Cabinet's 100-day plan, you have been asked to provide policy options to Cabinet to allow the sale of cold medicines containing pseudoephedrine [CAB-23-MIN-0468]

b) **Note** that an amendment to the Misuse of Drugs Act 1975 is required, to either reclassify or remove pseudoephedrine as a controlled drug

c) **Note** that removing pseudoephedrine as a controlled drug from the Misuse of Drugs Act 1975 would inhibit the ability of the New Zealand Customs Service to control illicit importations

d) **Note** that reclassifying pseudoephedrine from a Class B to a Class C controlled drug will enable the sale of pseudoephedrine-based cold medicines without a prescription, while also retaining appropriate border controls

e) **Agree** to either:

Option 1: Introduce a Bill to reclassify pseudoephedrine from a Class B to a Class C controlled drug (**recommended**) **Yes/No**

Option 2: Introduce a Bill to remove pseudoephedrine as a controlled drug from the Misuse of Drugs Act 1975 **Yes/No**

f) **Note** that for both options, the MoDA Amendment Bill can be introduced within the 100 days

g) **Note** that to allow the sale of pseudoephedrine products without a prescription, its classification under the Medicines Regulations 1984 would need to be changed

h) **Note** that determining the classification of pseudoephedrine under the Medicines Regulations 1984 should be informed by an appropriate assessment of clinical risk

i) **Agree** to either:

Option 1: Receive advice on pseudoephedrine's classification under the Medicines Regulations 1984, informed by limited assessment of clinical risk, on 17 January 2024. This will allow for the gazettal of the medicine's classification within the 100 days. **Yes/No**

Option 2: Receive advice on pseudoephedrine's classification under the Medicines Regulations 1984, following input from a clinical advisory group, in March 2024. (**recommended**) **Yes/No**

j) **Note** that your decision on when to receive advice on pseudoephedrine's classification under the Medicines Regulations 1984 will not impact the ability to introduce the MoDA Amendment Bill within the 100 days

k) **Note** that as product approvals for pseudoephedrine have lapsed, new approvals will be required for products to be available without prescription

l) **Note** that early information from suppliers suggests that they will not be able to supply pseudoephedrine products to New Zealand for up to a year due to manufacturing lead times

m) **Note** that the Ministry of Health | Manatū Hauora will provide you with a draft Cabinet paper to progress your chosen option on 17 January 2024.

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 15 December 2023

Hon David Seymour
Associate Minister of Health
Date: 20/12/23

Allowing access to pseudoephedrine

Background

The Coalition Government's commitment

10. Included in the Coalition Agreement between the National Party and the ACT Party is the policy to "allow the sale of cold medication containing pseudoephedrine". This policy is also listed as an action in the Coalition Government's plan for its first 100 days [CAB-23-MIN-0468].

11. You have been asked to report back to Cabinet by the end of January 2024, with policy proposals to allow access to pseudoephedrine products.

What is pseudoephedrine?

12. Pseudoephedrine is a substance that can be used alone or in combination with other medicines to treat nasal congestion resulting from a cold, flu or allergy. It works by stimulating nerve endings to release the chemical norepinephrine, which causes the blood vessels to constrict (narrow). This reduces the amount of fluid released from the vessels, resulting in less swelling and less mucus production in the nose.

13. Most adults and children aged 12 years and over can take pseudoephedrine, however it is not recommended for use in patients with severe high blood pressure or coronary heart disease, and may worsen conditions such as diabetes, glaucoma and kidney problems.

Access to pseudoephedrine in New Zealand and overseas

14. In New Zealand access was strictly limited in 2011, when pseudoephedrine was scheduled as a Class B2 controlled drug under the Misuse of Drugs Act 1975, and a prescription medicine under the Medicines Regulations 1984, due to concerns regarding its illicit use in the manufacture of methamphetamine.

15. Only registered medical practitioners can currently prescribe products containing pseudoephedrine. Medical practitioners rarely prescribe pseudoephedrine, and as a result, all manufacturers have allowed their product approvals to lapse. This means there are currently no pseudoephedrine products available in New Zealand.

16. In overseas jurisdictions such as Australia, the United Kingdom (UK), the United States (US) and Canada, pseudoephedrine-based medicines can be purchased without a prescription under the supervision of a registered pharmacist. Certain jurisdictions control access to pseudoephedrine by limiting the dose available for purchase without a prescription (Australia, UK), restricting the monthly purchase quantity (US), and requiring proof of identity to purchase products (all above countries).

17. Some jurisdictions also make use of electronic tracking systems to monitor sales of non-prescription products containing pseudoephedrine. In Australia and many US states, legislation requires all pharmacies that sell over-the-counter (OTC) medications containing pseudoephedrine to participate in an electronic monitoring programme. There is no equivalent electronic tracking system in New Zealand.

18. In some jurisdictions such as the Netherlands, pseudoephedrine is not approved as a medicine due to concerns about adverse cardiac side effects.

Precursor classification

19. In line with the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988), pseudoephedrine is also listed in Schedule 4 (Precursor Substances) of the Misuse of Drugs Act 1975. Precursor substances are substances that can be used in the manufacture of illicit drugs.

20. It is an offence to knowingly import or export precursor substances for unlawful use (e.g., the production or manufacture of a controlled drug). The New Zealand Customs Service has advised us that they can intercept a delivery of precursor substances only if they have obtained evidence that it is unlawfully imported.

21. Importing a controlled drug requires a licence from an approved supplier, which provides Customs an additional safeguard to prevent illicit supply.

What is required to allow access to pseudoephedrine in New Zealand?

22. Two regulatory changes are required before pseudoephedrine can be sold in New Zealand without a prescription:

    a. an amendment to the Misuse of Drugs Act 1975, to either reclassify or remove pseudoephedrine as a controlled drug

    b. a change to pseudoephedrine's classification as a prescription medicine under the Medicines Regulations 1984.

Amending the Misuse of Drugs Act 1975, to reclassify or remove pseudoephedrine as a controlled drug

23. Pseudoephedrine is currently classified under the Misuse of Drugs Act 1975 as a Class B2 controlled drug as well as a precursor substance. An amendment to the Misuse of Drugs Act 1975 would be required to allow the sale of cold medicines containing pseudoephedrine without a prescription.

24. There are two options to amend the Misuse of Drugs Act 1975:

    a. **Option 1 (recommended):** Reclassify pseudoephedrine as a Class C controlled drug. Effectively, this option would reinstate the classification of pseudoephedrine under the Misuse of Drugs Act 1975 that was in place prior to 2011.

    b. **Option 2:** Remove pseudoephedrine as a controlled drug.

25. Both options would retain the classification of pseudoephedrine as a precursor substance under Schedule 4 of the Misuse of Drugs Act 1975. As a precursor substance it could be seized at the border, however this would be more difficult for Customs to detect.

Implications: Domestic manufacture of methamphetamine

26. We have received advice from the National Drug Intelligence Bureau (NDIB) that increasing access to pseudoephedrine in New Zealand may increase the domestic manufacture of methamphetamine.

27. Currently in New Zealand, a significant proportion of the market for methamphetamine is supplied by importations of finished product, which are facilitated by organised crime groups (OCGs) in Asia, the Americas, and the Middle East.

28. The supply of methamphetamine in New Zealand is supplemented by domestic manufacture through clandestine laboratories (clan labs). In 2022, 62 illicit drug clan labs were detected in New Zealand, 90% of which manufactured methamphetamine.

29. Allowing the sale of cold medicines containing pseudoephedrine without a prescription will reinstate a supply source for the precursor substance. There is a risk that both pre-existing and new manufacturers will look to obtain pseudoephedrine from pharmacies. As a consequence, the domestic manufacture of methamphetamine may increase.

Implications: Illicit importations of pseudoephedrine

30. We have received advice from New Zealand Police and the New Zealand Customs Service that removing pseudoephedrine as a controlled drug would restrict their ability to seize importations of pseudoephedrine.

31. Under **option 1**, suppliers would need a licence to import and/or export pseudoephedrine, meaning that the New Zealand Customs Service can intercept all unlicensed shipments.

32. Under **option 2**, suppliers would not require a licence to import and/or export pseudoephedrine. To seize shipments, the New Zealand Customs Service would require evidence that the imported pseudoephedrine will be used in the manufacture of methamphetamine. The New Zealand Customs Service has advised us that this option will make it harder for them to intercept illicit importations of pseudoephedrine.

Changing the classification of pseudoephedrine as a medicine

33. Pseudoephedrine is currently classified under the Medicines Regulations 1984 as a prescription medicine. To be able to access pseudoephedrine without a prescription, the medicine's classification will need to be changed.

34. The Minister of Health or their delegate may classify medicines by notice in the *Gazette*.

35. The Medicines Act 1981 defines three classifications of medicines, each with a different level of control:

    a. **Prescription medicines** may be supplied only on the prescription of an authorised prescriber.

    b. **Restricted medicines** (also known as pharmacist-only medicines) may be sold without a prescription, but their sale must be made by a registered pharmacist in a pharmacy or hospital, and the details of the sale must be recorded.

c. **Pharmacy-only medicines** may only be sold in a community or hospital pharmacy, and their sale may be made by any salesperson.

36. If a medicine is not classified, then it defaults to general sale (e.g., can be sold in supermarkets). The classification of medicines can include a number of conditions, including those to do with packaging and dosage.

Process to amend the classification of medicines

37. The usual process for amending the classification of a medicine would involve consideration of advice from the Medicines Classification Committee (MCC). The MCC is an advisory committee that makes recommendations to the Minister of Health regarding the classification of medicines as prescription, restricted or pharmacy-only.

38. The process ensures that items for classification undergo formal consultation, including the opportunity for stakeholders to object to any recommendations made by the MCC.

39. This process can take up to 6 months due to the extensive public consultation process. However, there is no statutory requirement for you to seek advice from the MCC.

40. There are two options to provide you with advice on appropriate medicine classification, in a timely manner:

a. **Option 1:** We could provide advice on the classification of pseudoephedrine under the Medicines Regulations 1984 on 17 January 2024, with the draft Cabinet paper seeking approval for the amendment to the Misuse of Drugs Act 1975. Due to the timeframe this advice would be informed by limited assessment of clinical risk.

b. **Option 2 (recommended):** We could provide advice in March 2024, which has been informed by a clinical advisory group.

41. The decision to change the classification of pseudoephedrine under the Medicines Regulations has no funding implications for Pharmac.

Clinical input will ensure we consider sector concerns

42. Officials held a targeted focus group to further understand the views of pharmacists and identify any measures that could be taken to support and protect pharmacists.

43. Some pharmacists have raised concerns that reintroducing products containing pseudoephedrine will increase the risk of robberies and ram raids. Officials will investigate if the protections offered to shops and dairies through the Retail Crime Prevention Fund could be extended to community pharmacies.

44. A number of issues were also raised regarding pharmacist workload, and what guidance will be required to support the changes. Advice on these matters will be provided to you with the recommendations on medicine classification.

Approval process for products containing pseudoephedrine in New Zealand

45. Prior to 2011, there were a number of approved products containing pseudoephedrine marketed in New Zealand. Following the 2011 classification decision, pharmaceutical companies allowed their product approvals to lapse.

46. Regulatory changes will allow the supply of pseudoephedrine without a prescription, which will incentivise suppliers' re-entry to the New Zealand market.

47. As there are currently no approved pseudoephedrine products, suppliers will need to apply for approval by Medsafe's product approval process. The product approval process is an important part of the safety assurance process. It is vital that the products imported into New Zealand meet international standards for quality, safety and efficacy.

Why can we not import medicines approved by other jurisdictions?

48. Many pseudoephedrine-based products available overseas do not closely resemble the products that were previously approved in New Zealand, in terms of manufacturing processes and sites, labelling, and indications.

49. The Medicines Act 1981 defines these products as 'new medicines' due to the lack of regulatory or market activity for more than 5 years. Therefore, pharmaceutical companies will be required to make an application to Medsafe for consent for distribution (called a New Medicine Application; NMA).

Approval process is dependent on suppliers

50. The NMA process is initiated by pharmaceutical companies and thus dependent on their interest and ability to supply products in New Zealand.

51. Early information from pharmaceutical companies suggests that they may need up to 12 months to supply New Zealand due to manufacturing lead times. It will be up to companies to assess if they can obtain small quantities (e.g., from another market such as Australia). Medsafe is engaging with industry representation groups to keep them informed of progress.

52. We are advising an expedited medicine classification process as suppliers will want certainty about the rules under which pseudoephedrine can be supplied in New Zealand. This means that they will likely wait for confirmation of pseudoephedrine's classification as a medicine before considering whether to make an application.

Provisional product approval

53. To enable timely access to pseudoephedrine products, Medsafe is considering options for expedited approval pathways such as provisional approval. This process will ensure the quality of the product that is proposed to be supplied in New Zealand.

54. Medsafe will work with companies to implement a phased approach to the supply of pseudoephedrine products to ensure that Medsafe's technical resources can be managed, allowing for the approvals of other medicines.

Next steps

55. A draft Cabinet paper to seek approval to introduce a Bill to amend the Misuse of Drugs Act 1975 will be provided to you on 17 January 2024.

56. We will provide you with advice on the medicines classification (in accordance with your decision on required clinical input), and advice on the product approval process.

ENDS.

Minister's Notes

I am very interested in advice on expediting approval of the medicines given

a.) They were approved previously, and;

b.) The Govt. is committed to ~~strong~~ expediting any medicine approved by two peers.

What are our options for resolving prior approvals (perhaps by legislation), or accepting the advice of the jurisdictions?

Jarrod.