Briefing

Draft Cabinet paper to allow access to pseudoephedrine

Date due to MO:	12 January 2024	**Action required by:**	15 January 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2023034337
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

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Minister's office to complete:

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☐ See Minister's Notes	☐ Withdrawn	

Comment:

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To:	Hon David Seymour, Associate Minister of Health		

Purpose of report

1. This briefing provides you with a draft Cabinet paper seeking approval to amend the Misuse of Drugs Act 1975 and the Medicines Regulations 1984 to allow access to pseudoephedrine-based cold and flu products.

Background

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

3. On 15 December 2023, we provided you with advice on the options to achieve this commitment [H2023033231 refers], and you agreed to:

   a. reclassify pseudoephedrine from a Class B to a Class C controlled drug under the Misuse of Drugs Act 1975

   b. receive advice on the classification of pseudoephedrine under the Medicines Regulations 1984.

4. The attached draft Cabinet paper seeks approval to:

   a. draft a Bill to reclassify pseudoephedrine as a Class C3 controlled drug under the Misuse of Drugs Act 1975

   b. draft amendment regulations to reclassify pseudoephedrine as a restricted medicine under the Medicines Regulations 1984.

Changing the classification of pseudoephedrine

Controlled drug classification

5. The attached draft Cabinet paper proposes amending the Misuse of Drugs Act 1975 to reclassify pseudoephedrine from a Class B controlled drug to a Class C controlled drug.

6. Specifically, the proposed classification for pseudoephedrine is as a Class C3 (partially exempt) controlled drug. Class C3 drugs are exempt from many of the requirements for controlled drugs that can inhibit supply for therapeutic purposes.

Medicine classification

7. In response to our previous advice, you agreed to receive advice on pseudoephedrine's classification under the Medicines Regulations 1984, informed by limited assessment of clinical risk, on 17 January 2024.

8. The Minister of Health may temporarily classify medicines by notice in the *New Zealand Gazette* (or delegate this decision to the Director-General of Health), or permanently by amending Schedule 1 of the Medicines Regulations 1984.

9. We recommend changing the classification of pseudoephedrine through an amendment to the Medicines Regulations 1984 instead of a Gazette notice. The classification made by Gazette notice needs to be renewed every six months to maintain the classification and would eventually need to be provided for in regulation. Amending the regulations would provide more certainty for suppliers.

10. We recommend a classification of "restricted" because this option would allow pharmacists to monitor purchasing and address any risks to individual consumers.

Statutory consultation requirement

11. Before proposing amendments to the Medicines Regulations 1984, section 105 of the Medicines Act 1981 requires you to consult with "such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations".

12. To inform our advice on the appropriate medicine classification, 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.

13. We also sought the views of clinicians through the Ministry'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.

14. This fulfils the consultation requirements under section 105 of the Medicines Act 1981.

15. The majority of these stakeholders expressed the view that the appropriate classification for pseudoephedrine-based cold and flu products is as "restricted" medicines. It was also noted that this classification would likely increase the the workload for pharmacists.

16. In preparing our advice, we have also consulted with Health New Zealand, New Zealand Police, the National Drug Intelligence Bureau, Ministry of Justice, and the New Zealand Customs Service.

Process for approving new pseudoephedrine products

17. Our advice in December 2023 outlined that a New Medicine Application process will be required to approve any pseudoephedrine products for sale in New Zealand. This is because the previous approvals have lapsed and there has been no market activity for more than five years.

18. The Medicines Act 1981 provides two pathways for product approval: provisional approval (that allows for supply of the product while final approval is sought) and full

approval. The pathway is dependent on the choice made by the supplier, the information provided, and the risk the medicine poses.

19. Medsafe advises that pseudoephedrine-based products for cold and flu are used around the world and the benefit risk profiles of these products are well known. Therefore, Medsafe will concentrate on the manufacturing and quality of the products to be supplied in New Zealand. This is a pragmatic way to ensure New Zealanders receive international standard medicines rather than poor quality or substandard batches. Concentrating only on quality aspects makes the approval process much faster also, although the speed is dependent on the company supplying the data.

20. To achieve this in the fastest way possible, Medsafe advises it can make use of the provisional pathway available under section 23 of the Medicines Act 1981. Under the provisional consent pathway, the company will only need to update its data dossier on the manufacturing and quality of the products. Medsafe then evaluates the manufacturing data to ensure the company can supply product that consistently meets international standards.

21. Even with a provisional consent pathway, the overall timeframe for products to become available for purchase is largely dependent on suppliers. When the Cabinet decision is announced, we anticipate pharmaceutical companies will prepare to apply to Medsafe for provisional approval. Medsafe is happy to discuss any aspects of this pathway further if you wish.

22. We will provide you with further advice and options to improve medicine regulatory timeframes for the approval of new medicines into New Zealand, including the Government's commitment to expedite the approval of medicines approved in similar jurisdictions, early this year.

Next steps

23. The Parliamentary Counsel Office advises that for an amendment bill to be introduced within the 100-day timeframe, Cabinet approval should be sought no later than 23 January 2024.

24. To achieve this, the final version of the attached Cabinet paper will need to be lodged by 10am on 15 January 2024 to be considered by the Cabinet Business Committee on 17 January 2024.

25. Following Cabinet approval, these changes should be publicly announced to provide certainty of the regulatory settings to the public and potential suppliers. We will work with your office to draft communications material.

Recommendations

We recommend you:

a) **Note** that to allow access to pseudoephedrine-based cold and flu products, they will need to be reclassified under the Medicines Regulations 1984 and the Misuse of Drugs Act 1975

b) **Note** that you previously agreed to introduce a Bill to reclassify pseudoephedrine from a Class B to a Class C controlled drug under the Misuse of Drugs Act 1975

c) **Note** that the attached draft Cabinet paper proposes that pseudoephedrine be reclassified as a Class C3 (partially exempt) controlled drug under the Misuse of Drugs Act 1975

d) **Note** that we advise that the statutory consultation requirements for amending the Medicine Regulations 1984, under section 105 of the Medicines Act 1981, have been met

e) **Agree** to amend the Medicines Regulations 1984 to change the classification of pseudoephedrine-based cold and flu products from prescription to restricted medicines **Yes/No**

f) **Note** that to introduce a Bill to amend the Misuse of Drugs Act 1975 within the 100-day timeframe, the attached Cabinet paper will need to be lodged by 10am on 15 January 2024.

Maree Roberts
Acting Director-General of Health
Date: 11/01/24

Hon David Seymour
Associate Minister of Health
Date: 15/1/24

ENDS.

Minister's Notes