Cabinet

Minute of Decision

Report of the Cabinet Legislation Committee: Period Ended 16 February 2024

On 19 February 2024, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 16 February 2024:

LEG-24-MIN-0002	**Misuse of Drugs (Pseudoephedrine) Amendment Bill and Medicines (Pseudoephedrine) Amendment Regulations** Portfolio: Associate Health (Hon David Seymour)	CONFIRMED

Out of scope

Diana Hawker
Acting Secretary of the Cabinet

LEG-24-MIN-0002

Cabinet Legislation Committee

Minute of Decision

Misuse of Drugs (Pseudoephedrine) Amendment Bill and Medicines (Pseudoephedrine) Amendment Regulations

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

On 15 February 2024, the Cabinet Legislation Committee:

1 **noted** that in January 2024, the Cabinet 100-Day Plan Committee agreed to proposed legislative changes needed as the first step to actioning the Government's commitment to allow the sale of cold medicines containing pseudoephedrine [100-24-MIN-0003];

2 **noted** that the Misuse of Drugs (Pseudoephedrine) Amendment Bill (the Bill) reclassifies pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug;

3 **noted** that the Bill is currently not assigned to a legislative priority category because the 2024 Legislation Programme is still being developed;

4 **noted** that the Bill is proposed to hold a category 3 priority on the 2024 Legislation Programme (to be passed by the end of 2024);

5 **approved** the Misuse of Drugs (Pseudoephedrine) Amendment Bill [PCO 26060/5.1] for introduction, subject to the final approval of the government caucus and sufficient support in the House of Representatives;

6 **agreed** that the Bill be introduced under urgency on 20 February 2024;

7 **agreed** that the government propose that the Bill be referred to the Health Select Committee;

8 **noted** that the Associate Minister of Health (Hon David Seymour) intends to move a motion that the Bill be considered by the Health Select Committee for 1 month;

9 **noted** that the Medicines (Pseudoephedrine) Amendment Regulations 2024 reclassify cold and flu medicines containing pseudoephedrine as restricted medicines;

10 **authorised** the submission to the Executive Council of the Medicines (Pseudoephedrine) Amendment Regulations 2024 [PCO 26090/3.0];

11 **noted** that the Medicines (Pseudoephedrine) Amendment Regulations come into force on 21 March 2024;

12 **noted** that pharmaceutical companies will decide if and when to apply to Medsafe for product approval.

Rebecca Davies
Committee Secretary

Present:
Rt Hon Winston Peters
Hon Simeon Brown
Hon Tama Potaka
Hon Nicole McKee
Hon Casey Costello
Hon Simon Watts
Hon Andrew Bayly
Scott Simpson, MP (Senior National Whip)
Todd Stephenson, MP (ACT Whip)
Jamie Arbuckle, MP (New Zealand First Whip)

Officials present from:
Officials Committee for LEG
Office of the Leader of the House
Office of the Minister of Climate Change

In Confidence

Office of the Associate Minister of Health

Cabinet Legislation Committee

Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024: Approval for Introduction

Proposal

1 This paper seeks approval for introduction of the Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024. It also recommends the Cabinet Legislation Committee authorise the submission to the Executive Council of the Medicines (Pseudoephedrine) Amendment Regulations 2024.

Policy

2 The Government's 100-day plan includes a commitment to "allow the sale of cold medication containing pseudoephedrine" [CAB-23-MIN-0468 refers]. In January 2024, Cabinet agreed to proposed legislative changes needed to fulfil the commitment [CAB-24-MIN-0002 refers].

3 The proposed legislative changes are the first step to allowing the sale of cold and flu medicines containing pseudoephedrine without a prescription.

Amendments to the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977

4 The Bill reclassifies pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug. This will enable the supply of cold and flu medicines containing pseudoephedrine without a prescription, while also retaining appropriate border controls. Suppliers will still need a licence to import and export pseudoephedrine products, and Customs can intercept shipments of unlicensed imports.

5 When the Bill is enacted, it will continue to be unlawful to import for personal use by mail, or by online shopping. 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.

6 Class C3 (partially exempted) controlled drugs are exempted from many requirements that inhibit supply for therapeutic purposes or that duplicate requirements in the Medicines Regulations 1984. The exemptions are set out in the Misuse of Drugs Regulations 1977. The Bill makes consequential amendments to the Misuse of Drugs Regulations 1977 (revoking obsolete pseudoephedrine-specific regulations).

Amendments to the Medicines Regulations 1984

7 These amendments reclassify pseudoephedrine-containing cold and flu products as restricted medicines. A restricted classification means customers can purchase the products at a pharmacy and will need to do so by way of a face-to-face transaction with a pharmacist.

8 These regulatory changes will encourage pharmaceutical companies to submit applications to Medsafe for product approval to sell their pseudoephedrine-containing cold and flu medicines in New Zealand. However, pharmaceutical companies ultimately decide if and when to apply to Medsafe for product approval.

Impact analysis

9 A regulatory impact statement (RIS) was submitted to the Cabinet 100-Day Plan Committee with the Cabinet policy paper. The RIS supported the proposal while noting the uncertainties and risks.

10 The RIS noted that the impact analysis had been limited by a lack of extensive consultation with affected stakeholders.

Compliance

11 The Bill and associated amendments to regulations comply with:

11.1 the principles of the Treaty of Waitangi;

11.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;

11.3 the disclosure statement requirements;

11.4 the principles and guidelines set out in the Privacy Act 2020;

11.5 relevant international standards and obligations;

11.6 the Legislation Guidelines (2021 edition) maintained by the Legislation Design and Advisory Committee.

Consultation

12 When preparing policy advice and the RIS, the Ministry of Health (the Ministry) consulted with Health New Zealand, New Zealand Police, New Zealand Customs Service, Ministry of Justice, and the Department of the Prime Minister and Cabinet.

13 The Ministry conducted limited consultation with representatives of affected stakeholder groups. The consultation highlighted the impacts, risks and mitigations as detailed in the RIS. I am satisfied that this consultation meets the statutory prerequisites under section 105 of the Medicines Act 1981 for consultation on amendments to Medicines Regulations.

Binding on the Crown

14 The primary legislation, the Misuse of Drugs Act 1975, is binding on the Crown.

Creating new agencies or amending law relating to existing agencies

15 The legislation does not create a new agency or amend the law relating to existing agencies.

Allocation of decision-making powers

16 The draft legislation does not involve the allocation of decision-making powers between the executive, the courts, and tribunals.

Associated regulations

17 Regulations are not required to bring the Bill into operation.

Other instruments

18 The proposed Bill does not include any provision empowering the making of other instruments that are deemed to be legislative instruments or disallowable instruments (or both).

Definition of Minister/department

19 The Bill does not contain a definition of Minister, department (or equivalent government agency), or chief executive of a department (or equivalent position).

Commencement of legislation

20 The Bill will come into force on the day after the date of Royal assent.

Parliamentary stages

21 The Bill is intended to be introduced under urgency on 20 February 2024.

22 The Bill will be referred to the Health Select Committee, and I intend to move a motion that the Bill be considered by the Committee for 1 month.

Timing and 28-day rule

23 I am not seeking a waiver of the 28-day rule.

24 The Medicines (Pseudoephedrine) Amendment Regulations 2024 will be notified in the New Zealand Gazette as soon as possible after officials are informed of the Executive Council's agreement. The regulations will come into force 28 days after they are notified in the Gazette.

Regulations Review Committee

25 The Parliamentary Counsel Office does not consider that there are grounds for the Regulations Review Committee to draw this instrument or regulations to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

26 The draft regulations have been certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

Publicity

27 I intend to announce these changes following Cabinet agreement.

28 Medsafe will invite expressions of interest from pharmaceutical companies looking to apply for product approval.

Proactive Release

29 I intend proactively releasing this paper, with any redactions as appropriate under the Official Information Act 1982.

Recommendations

I recommend that the Legislation Committee:

1 **note** that in January 2024, Cabinet agreed to proposed legislative changes needed as the first step to actioning the Government's commitment to allow the sale of cold medicines containing pseudoephedrine [CAB-24-MIN-0002 refers];

2 **note** that the Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024 will reclassify pseudoephedrine from a Class B2 controlled drug to a Class C3 (partially exempted) controlled drug;

3 **note** that the Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024 is currently not assigned to a legislative priority category because the 2024 Legislation Programme is still being developed;

4 **agree** that the Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024 is proposed to hold a category 3 priority on the 2024 Legislation Programme (to be passed by the end of 2024);

5 **approve** the Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024 for introduction;

6 **agree** that the Bill be introduced under urgency on 20 February 2024;

7 **agree** that the Misuse of Drugs (Pseudoephedrine) Amendment Bill 2024 will be referred to the Health Select Committee

8 **note** that I intend to move a motion that the Bill be considered by the Health Select Committee for 1 month;

9 **note** that the Medicines (Pseudoephedrine) Amendment Regulations 2024 reclassify cold and flu medicines containing pseudoephedrine as restricted medicines;

10 **authorise** the submission to the Executive Council of the Medicines (Pseudoephedrine) Amendment Regulations 2024;

11 **note** that the Medicines (Pseudoephedrine) Amendment Regulations 2024 will come into force 28 days after notification in the New Zealand Gazette;

12 **note** that pharmaceutical companies will decide if and when to apply to Medsafe for product approval.

Authorised for lodgement

Hon David Seymour

Associate Minister of Health