

Misuse of Drugs (Pseudoephedrine) Amendment Bill

Government Bill

Explanatory note

General policy statement

In accordance with the Government's commitment to allow the sale of cold and flu medication containing pseudoephedrine, the purpose of this Bill is to change the classification of pseudoephedrine as a controlled drug. This Bill reclassifies pseudoephedrine from a Class B2 to a Class C3 controlled drug under the Misuse of Drugs Act 1975, so that cold and flu products containing pseudoephedrine can be sold in pharmacies without a prescription. The different classes of controlled drugs are described in regulation 25(2) of the Misuse of Drugs Regulations 1977.

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at <http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2024&no=21>.

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 12 January 2024 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

- <https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements>
- <https://treasury.govt.nz/publications/informationreleases/ris>

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 is the commencement clause and provides that the Bill comes into force on the day after Royal assent.

Clause 3 provides that the principal Act amended by this Bill is the Misuse of Drugs Act 1975.

Part 1

Amendments to principal Act

Clause 4 amends Schedule 2 of the principal Act to remove pseudoephedrine from the list of Class B controlled drugs. Schedule 2 of the principal Act lists drugs that are classified as having a high risk of harm. This clause also makes a related exemption for the isomers of ephedrine.

Clause 5 amends Schedule 3 of the principal Act to add pseudoephedrine to the list of Class C controlled drugs. Schedule 3 lists drugs that are classified as having a moderate risk of harm. Pseudoephedrine is being added to Part 3 of Schedule 3, which means it will be a partially exempted drug as defined under the Misuse of Drugs Regulations 1977. This clause also makes a related exemption for the isomers of pseudoephedrine.

Part 2

Amendments to Misuse of Drugs Regulations 1977

Clause 6 provides that *Part 2* amends the Misuse of Drugs Regulations 1977.

Clause 7 replaces the definition of partially exempted drug to remove the dosage limitation that currently applies to pseudoephedrine in order for it to be considered a partially exempted drug. This means that pseudoephedrine will be a partially exempted drug regardless of dosage, in the same way as the other partially exempted drugs listed in Part 3 of Schedule 3 of the Misuse of Drugs Act 1975.

Clause 8 amends regulation 20 to remove a restriction related to pseudoephedrine, which will be obsolete if pseudoephedrine becomes a restricted medicine under the Medicines Regulations 1984.

Clause 9 amends regulation 28 to align with the amended definition of partially exempted drug under *clause 7*.

Hon David Seymour

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The Parliament of New Zealand enacts as follows:

- 1 Title**
This Act is the Misuse of Drugs (Pseudoephedrine) Amendment Act **2024**.
- 2 Commencement**
This Act comes into force on the day after Royal assent. 5
- 3 Principal Act**
This Act amends the Misuse of Drugs Act 1975.

Part 1 Amendments to principal Act

4 Schedule 2 amended

- (1) In Schedule 2, Part 2, clause 1, delete “**Pseudoephedrine**”.
- (2) In Schedule 2, Part 2, clause 2, after “designation”, insert “, except pseudoephedrine”. 5

5 Schedule 3 amended

- (1) In Schedule 3, Part 3, clause 1, insert in its appropriate alphabetical order:
Pseudoephedrine
- (2) In Schedule 3, Part 3, clause 2, after “designation”, insert “, except ephedrine”. 10

Part 2 Amendments to Misuse of Drugs Regulations 1977

6 Principal regulations

This Part amends the Misuse of Drugs Regulations 1977.

7 Regulation 2 amended (Interpretation) 15

In regulation 2(1), replace the definition of **partially exempted drug** with:
partially exempted drug means a controlled drug that is for the time being named or described in clauses 1 to 5 of Part 3 of Schedule 3 of the Act

8 Regulation 20 amended (Supply and administration of controlled drugs without prescription) 20

- (1) In regulation 20(2)(a), delete “, subject to subclause (3)”.
- (2) Revoke regulation 20(3).

9 Regulation 28 amended (Custody of controlled drugs)

Replace regulation 28(4)(e) with:

- (e) pseudoephedrine: 25