

In Confidence

Office of the Minister of Health

Chair, Cabinet Legislation Committee

Misuse of Drugs (Classification and Presumption of Supply) Order 2022 and Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022

Proposal

- 1 This paper seeks approval to submit the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 and the Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022 to the Executive Council.

Policy

- 2 On 17 May 2021, Cabinet agreed to classify or reclassify 49 substances as controlled drugs to ensure they are regulated in line with the risk of harm they pose to individuals and society [refer CAB-21-MIN-0167]. These substances are becoming more available in New Zealand and have been implicated in multiple deaths and hospital admissions.
- 3 Once classified as controlled drugs under the Misuse of Drugs Act 1975 (the Act) increased penalties can be imposed and consequently Police and Customs will have increased search and seizure powers to disrupt the supply of the substances. Interrupting supply to those who may use them harmfully is a key part of a health response to reduce drug related harm.
- 4 Substances are classified as controlled drugs under the Act according to their risk of harm. Class A (Schedule 1) drugs are considered to pose a very high risk of harm, Class B (Schedule 2) a high risk of harm, and Class C (Schedule 3) a moderate risk of harm. There is a separate Schedule 4 for precursor substances (chemicals that can be used to manufacture other drugs such as methamphetamine and fentanyl).
- 5 The Expert Advisory Committee on Drugs (the Expert Advisory Committee) established under the Act advises the Minister of Health on drug classification matters. It carries out medical and scientific evaluations of controlled drugs and any other narcotic or psychotropic substances.
- 6 The Act requires me as Minister of Health to consult with, and consider any advice given by, the Expert Advisory Committee, and have regard to the matters set out in sections 4B(2) and (4) of the Act before recommending that an Order in Council is made to amend the schedules of the Act. The Expert Advisory Committee has recommended, and I considered the matters in the relevant sections of the Act and agreed, that the 49 substances be classified or reclassified in the schedules to reflect their risk of harm.

- 7 The Expert Advisory Committee also recommended quantities be set for five groups of substances for which they will be presumed to be for supply and therefore for which heavier penalties can be imposed. This is based on the potency of the substance, how much tends to be used at one time, and international experience. This will help target importers, manufacturers and suppliers, and drive down supply.
- 8 As recommended by the Expert Advisory Committee, amendments are also proposed to be made to the Misuse of Drugs Regulations 1977. The amendments will relate to the prescription medicines fentanyl and tramadol, and:
- 8.1 exempt fentanyl from the requirement for the Minister of Health to approve its supply, administration or being prescribed; and
- 8.2 exempt tramadol from strict custody and storage requirements and included it in Schedule 1C of the Misuse of Drugs Regulations 1977 so that it can be prescribed by midwives (along with other health practitioners).
- 9 The intent of the amendments is to maintain legitimate therapeutic access to the prescription medicines in a similar way as prior to being classified but with tighter controls to minimise the risk they will be misused. Once classified, increased penalties can be imposed and more comprehensive search and seizure powers used to increase the risk of detection for importing, manufacturing and supply offending.
- 10 The amendments will come into force when the Order in Council is brought into force by commencement Order.
- 11 No new policy decisions are required.

Timing and 28-day rule

- 12 I am not seeking a waiver of the 28-day rule.
- 13 The Order in Council will come into force by a Commencement Order following approval by resolution of the House of Representatives pursuant to section 4A of the Misuse of Drugs Act 1975.

Compliance

- 14 The draft Order in Council complies with:
- 14.1 the principles of the Treaty of Waitangi;
- 14.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;
- 14.3 the principles and guidelines set out in the Privacy Act 2020;
- 14.4 relevant international standards and obligations; and

- 14.5 the Legislation Guidelines (2018 edition), which are maintained by the Legislation Design and Advisory Committee.
- 15 The setting of presumption of supply limits engages section 25(c) of the New Zealand Bill of Rights Act 1990 (right of everyone charged with an offence to be presumed innocent until proven guilty). The presumption of supply limits in the Act shifts the legal burden of proof to the accused to prove that they were not supplying the drugs.
- 16 Limitation of the right to be presumed innocent until proven guilty can be justified if there is a connection between the substance and either a high probability or near certainty that the quantity possessed was for supply. For example, if a substance is extremely potent, then it may be argued that a large amount is unlikely to be for personal use only, in which case the limitation may be justified.
- 17 New Zealand is a Party to the United Nations' Single Convention on Narcotic Drugs 1961, the Convention on Psychotropic Substances 1971 and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988. Many of the substances to be classified or reclassified are listed in the Conventions. New Zealand will meet its international obligations as a Party to the Conventions by classifying and reclassifying the substances.
- 18 In accordance with sections 4B(1)(a) and (3) of the Misuse of Drugs Act 1975 I have consulted with and considered advice given by the Expert Advisory Committee. I have also had regard to all matters set out in sections 4B(2) and (4) of the Misuse of Drugs Act 1975.

Regulations Review Committee

- 19 The Parliamentary Counsel Office does not consider 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

- 20 The draft Order in Council has been certified by Parliamentary Counsel Office as being in order for submission to Cabinet without reservation.

Impact analysis

- 21 The Regulatory Quality Team at the Treasury determined that the decisions sought in this paper are exempt from the requirement to provide a regulatory impact assessment. Most of the decisions are essential (the minimum necessary) to comply with international obligations that are binding on New Zealand, and where they are not, the associated impacts on businesses, individuals or not-for profit entities are minor.

Publicity

- 22 A communications plan will be prepared and will include steps to inform the pharmaceutical industry, pharmacies and health practitioners of the changes once the Order in Council is notified in the *Gazette*.

Proactive Release

- 23 I intend to proactively release this paper in accordance with Cabinet circular CO(18)4 once the Order in Council comes into effect.

Consultation

- 24 The New Zealand Police, Ministry of Justice, New Zealand Customs Service, the Department of Corrections and the Department of the Prime Minister and Cabinet were consulted, and feedback incorporated during the course of developing the policy, and this paper.

Recommendations

I recommend that the Cabinet Legislation Committee:

- 1 note that on 17 May 2021 Cabinet agreed:
 - 1.1 to classify or reclassify 49 substances as controlled drugs under the Misuse of Drugs Act 1975;
 - 1.2 to set quantities for some substances at and above which it is presumed they are for supply;
 - 1.3 to make three amendments in stand-alone regulations amending the Misuse of Drugs Regulations 1977 to ensure legitimate therapeutic access to tramadol and fentanyl is not hampered by their classification and reclassification, respectively [refer CAB-21-MIN-0167];
- 2 note that the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 will give effect to the decisions referred to in paragraph 1.1 and 1.2 above;
- 3 note that the Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022 will give effect to the decisions referred to in paragraph 1.3 above;
- 4 authorise the submission to the Executive Council of the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 and the Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022;
- 5 note that the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 will come into force by a Commencement Order following approval by resolution by the House of Representatives;
- 6 note that the Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022 will come into force when the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 is brought into force by Commencement Order;
- 7 note that under sections 4B(1)(a) and (3) of the Misuse of Drugs Act 1975 the Minister of Health is required to consult with and consider advice given by the Expert Advisory Committee, and have regard to all matters set out in sections

4B(2) and (4) of the Misuse of Drugs Act 1975 before recommending the making of an Order in Council under sections 4(1) and 4(1B) of the Misuse of Drugs Act 1975;

8 note my advice as Minister of Health that these requirements have been met.

Authorised for lodgement

Hon Andrew Little
Minister of Health

PROACTIVELY RELEASED