

Office of the Minister of Health

Chair

Cabinet Legislation Committee

**Misuse of Drugs (Classification and Presumption of Supply)  
Commencement Order 2022 and the Misuse of Drugs  
(Classification and Presumption of Supply) Amendment Order 2022**

**Proposal**

- 1 This paper seeks approval for the Misuse of Drugs (Classification and Presumption of Supply) Commencement Order 2022 (the commencement Order) and the Misuse of Drugs (Classification and Presumption of Supply) Amendment Order 2022 (the amendment Order) to be submitted to the Executive Council.
- 2 The effect of the commencement Order will be to bring into force the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 and the Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022.
- 3 The effect of the amendment Order will be to resolve a drafting error that was discovered in the Misuse of Drugs (Classification and Presumption of Supply) Order 2022.

**Policy**

- 4 The commencement Order is an administrative order and contains no policy that has not already been agreed to by Cabinet [CAB-21-MIN-0167].
- 5 Cabinet agreed to the classification and reclassification of 49 substances by Order in Council [CAB-22-MIN-0040 refers]. The Misuse of Drugs (Classification and Presumption of Supply) Order 2022 (the Order) and the Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022 (the amendment regulations) were made on 21 February 2022.
- 6 The Act requires that before the Order can be commenced, it must be approved by affirmative resolution of the House of Representatives. The House approved the Order by affirmative resolution on 5 May 2022.
- 7 The Order will create new labelling requirements for several prescription medicines. Once classified or reclassified, these medicines will require specific labelling to comply with the Misuse of Drugs Regulations 1977 and to be supplied lawfully. Medsafe has consulted with the pharmaceutical sector to arrive at a commencement timeframe that ensures the substances are appropriately classified in a timely manner while limiting any impact on the availability of important medicines.

- 8 I am proposing that there be three commencement dates for the Order. The first commencement date will be 15 December 2022, when the substances that do not require labelling changes will be added to the relevant Schedules of the Act. 45 of the 49 substances in the Order will be classified or reclassified on this date. This includes all the substances which are being added to Schedule 1 (Class A) of the Act, as they have been identified as posing a very high risk of harm it is important that they are classified as soon as possible.
- 9 The second commencement date will be 1 July 2023, when three substances will be added to the Schedules of the Act. These substances include fentanyl (being reclassified), zopiclone and zolpidem which will be classified as either Class B or C. The third commencement date will be 1 October 2023, when tramadol will be added to the Schedules of the Act.
- 10 This extended timeframe will enable manufacturers and suppliers of these medicines the time they need to ensure the required labelling is on their products. This includes updating labelling on existing stock where possible.
- 11 It has been discovered that an error was made in the drafting of the Order, the effect of which would mean that presumption of supply limits would not apply to some of the substances being classified. Parliamentary Counsel Office have advised that an amendment order is required to address this error.

### Timing and 28-day rule

- 12 The commencement Order will specify three dates for different parts of the Order to come into effect, 15 December 2022, 1 July 2023 and 1 October 2023. The first date will be more than 28 days after the commencement Order is gazetted.
- 13 The amendment Order will come into effect on 15 December 2022.

### Compliance

- 14 The Order and amendment regulations being brought into effect, comply 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 or 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 (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

## Regulations Review Committee

- 15 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

- 16 The Parliamentary Counsel Office has certified these Orders in Council as being in order for submission to Cabinet without reservation.

## Impact Analysis

- 17 The Regulatory Quality Team at the Treasury determined that the Order and amendment regulations which will be brought into effect by this commencement Order are exempt from the requirement to provide a Regulatory Impact Assessment. Most of the changes 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

- 18 Communication with relevant stakeholders in the pharmaceutical industry has been ongoing through the classification process, as their views were required to determine the proposed commencement timeline.
- 19 Further communications will be provided to pharmacy groups and health practitioners once the commencement Order is gazetted.

## Proactive release

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

## Consultation

- 21 The New Zealand Police, Ministry of Justice, New Zealand Customs Service, the Department of Corrections, the National Drug Intelligence Bureau and the Department of the Prime Minister and Cabinet were consulted on this proposal.
- 22 New Zealand Police commented that they would prefer the up-scheduling of fentanyl be included at the first commencement date. However, Police also noted that they have not seen a trend of increased illicit fentanyl use. The Ministry received no other objections to the proposed timeframes.

## Recommendations

I recommend that the Cabinet Legislation Committee:

- 1 note that on 17 May 2021 Cabinet agreed:

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- 1.1 to classify and reclassify 49 substances as controlled drugs under the Misuse of Drugs Act 1975;
- 1.2 to set quantities for some of those substances at and above which it is presumed they are for supply;
- 1.3 to amend the Misuse of Drugs Regulations 1977 to ensure legitimate therapeutic access to tramadol and fentanyl is not hampered by their classification and reclassification respectively [CAB-21-MIN-0167 refers];
- 2 note that the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 will give effect to the decisions referred to in recommendations 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 recommendation 1.3 above;
- 4 note that the Misuse of Drugs Act 1975 requires a classification order to be approved by affirmative resolution in the House of Representatives;
- 5 note that on 5 May 2022 the House made an affirmative resolution to approve the Misuse of Drugs (Classification and Presumption of Supply) Order 2022;
- 6 note that a drafting error was discovered in the Misuse of Drugs (Classification and Presumption of Supply) Order 2022, and that an amendment order is required to resolve the error;
- 7 authorise the submission to the Executive Council of the Misuse of Drugs (Classification and Presumption of Supply) Commencement Order 2022;
- 8 authorise the submission to the Executive Council of the Misuse of Drugs (Classification and Presumption of Supply) Amendment Order 2022.

Authorised for lodgement

Hon Andrew Little  
Minister of Health

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