

19 June 2023

Upcoming reclassification of fentanyl, tramadol, zopiclone and zolpidem

The Misuse of Drugs (Classification and Presumption of Supply) Order 2022 will change the classification of some prescription medicines under the Misuse of Drugs Act 1975. This is the result of a decision by Cabinet to either schedule or up-schedule some prescription medicines based on their risk of harm and advice received from the Expert Advisory Committee on Drugs.

From their respective commencement dates, the new controlled drug classification for these medicines will take effect and all activities, including prescribing and dispensing, will be subject to the requirements under the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977.

On 1 July 2023:

- fentanyl will be up-scheduled to a Class B1 controlled drug (from Class B3)
- zopiclone will be scheduled as a Class C5 controlled drug
- zolpidem will be scheduled as a Class C5 controlled drug.

On 1 October 2023:

- tramadol will be scheduled as a Class C2 controlled drug.

Whilst medicines may be scheduled or up-scheduled under the Misuse of Drugs Act 1975, they also retain their classification as prescription only medicines and must comply with all relevant requirements.

These classification changes are not connected to a recent review of safe opioid access that Manatū Hauora commenced in March 2023. This review may result in further changes to prescribing and dispensing regulations for controlled drugs. Manatū Hauora will provide updates on the progress of the review.

As a follow up from previous communications sent late last year, we thought it would be useful to provide further specific guidance in relation to the current legislation on these changes, including how these changes will affect prescribing and dispensing practice.

Guidance for prescribers

Fentanyl

There will be no changes to the prescribing requirements for fentanyl.

Cabinet has agreed to exempt fentanyl from ministerial approval requirements outlined under [regulation 22](#) of the Misuse of Drugs Regulations 1977 for the prescribing, supply and administration of fentanyl once it is scheduled as a Class B1 controlled drug.

Whilst there is no change to prescribing requirements, the change in classification for fentanyl will provide authorities with increased powers in instances of suspected illicit manufacturing and supply activity. This is in response to largely international evidence which suggests that fentanyl is increasingly being abused.

Zopiclone, zolpidem and tramadol

The scheduling of these medicines under the Misuse of Drugs Act 1975 will have an impact on who can continue to prescribe these medicines, as well as the quantity and period of supply.

Please refer to the attached practice points for further information.

We are aware that for some prescribers this change will significantly reduce the maximum period of supply that can be prescribed for these medicines. Manatū Hauora is currently reviewing these restrictions and will provide updates if there are likely to be further changes.

Guidance for pharmacists

Fentanyl

There will be no changes to the recording, storage or dispensing requirements for fentanyl when it is up-scheduled to a Class B1 controlled drug.

Zopiclone, zolpidem and tramadol

Transactions requiring zopiclone, zolpidem and tramadol will not be required to be recorded in a controlled drugs register, nor will they be required to be stored in a controlled drugs safe. However, there will be changes to the prescribing and dispensing of these medicines. Please refer to the attached practice points for further information.

Additional information

Manufacturers and sponsors will be making changes to their packaging to reflect these new classifications. Please ensure as part of good regulatory practice, stock with the old classification is supplied or dispensed first.

Consider printing out the attached document 'The classifications of some medicines are changing: what this means for you'. All regulatory changes described will come into force and will need to be adhered to from 1 July 2023 (for fentanyl, zopiclone, zolpidem) and 1 October 2023 (for tramadol).

If you have any further questions relating to these classification changes, please email RPA.Legislation@health.govt.nz.