

2 December 2022

Information for pharmacies and prescribers – upcoming changes to the classification of lisdexamfetamine, fentanyl, zopiclone, zolpidem and tramadol

Earlier this year, the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 was passed which scheduled or up-scheduled 49 substances under the Misuse of Drugs Act 1975 (the Act). These 49 substances include 5 medicines.

Further to the Order, a decision has now been made on the date the new classification will come into effect for each substance (the commencement date).

The affected medicines are listed below with their new classification and the date on which the change will commence:

on **15 December 2022**: **lisdexamfetamine** will be scheduled as a **Class B2**

on **1 July 2023**: **fentanyl** will be up-scheduled to **Class B1 (from Class B3)**
zopiclone and **zolpidem** will be scheduled as a **Class C5**

on **1 October 2023**: **tramadol** will be scheduled as a **Class C2**.

From the commencement date, 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 Act and the Misuse of Drugs Regulations 1977 (the Regulations).

Lisdexamfetamine

From the **15 December 2022** the following changes to practice will be legislatively required:

Prescribing

Under regulation 22 of the Regulations, Class B2 controlled drugs, require ministerial approval to prescribe, supply and administer to a named patient.

From the 15 December 2022, any prescriber wishing to prescribe lisdexamfetamine will require ministerial approval to prescribe for a named patient.

To apply for ministerial approval to prescribe lisdexamfetamine, please email Medicines Control at medicinescontrol@health.govt.nz.

Please note that under this legislation, ministerial approval is also required to supply and administer, and sufficient information should be provided with respect of this as part of the application process.

Medsafe is actively exploring the possibility of granting a 'blanket' ministerial approval to allow the prescribing, supply and administration of lisdexamfetamine in particular circumstances, to align with the 'blanket' ministerial approvals already in place for dexamphetamine and methylphenidate.

Storage

From 15 December 2022, lisdexamfetamine will be required to be stored in a controlled drugs safe.

Recording

From 15 December 2022, all transactions involving lisdexamfetamine will be required to be recorded in a Controlled Drug Register.

In addition, lisdexamfetamine will be subject to all other recording requirements such as the 6 monthly stocktakes required as at the close of business on 30 June and 31 December in every year.

Regulatory guidance for fentanyl, zopiclone, zolpidem and tramadol

Further regulatory guidance for fentanyl, tramadol, zopiclone and zolpidem will be provided to you closer to the commencement date when the new controlled drug classification takes effect.

Please note that the changes for fentanyl, zopiclone and zolpidem do not take effect until **1 July 2023** and tramadol until **1 October 2023**.

Links to legislation

For reference the relevant pieces of legislation can be accessed at:

- [Misuse of Drugs \(Classification and Presumption of Supply\) Order 2022](#)
- [Misuse of Drugs \(Classification and Presumption of Supply\) Commencement Order 2022](#).

If you have any questions relating to the upcoming classification change of lisdexamfetamine or any other of the classifications occurring next year, please send your queries via email to: RPA.Legislation@health.govt.nz.