Doctor employed by ketamine clinic has registration cancelled for unsafe prescribing

Key messages from the case

Doctors must ensure any medication they prescribe is safe, appropriate, and in the best interests of the patient. If medications are prescribed outside an accepted therapeutic standard, patients must clearly understand this and provide informed consent. Failing to prescribe appropriately can put patient safety at risk and may have significant professional consequences, as a case involving a ketamine clinic illustrates.

Details of the decision

Prescribing

Dr C was employed by a medical clinic that offered ketamine, an S8 medication, to treat major depressive illnesses. The clinic only offered ketamine and no other treatments were available. At the time ketamine was not approved by the Therapeutic Goods Administration (TGA) for use in depressive illnesses and was not indicated for depressive symptoms. Some research had commenced, but there was no established protocol for its use as a treatment for depression.[1]

Dr C had previously been practising primarily as an orthopaedic Career Medical Officer for many years and had almost no experience outside public hospital employment before working in the clinic. He did not have any specialist training or qualifications.

When his prescribing was investigated, it emerged that he had prescribed ketamine to 171 patients. In some cases, patients were prescribed doses to self-administer.

It was alleged his prescribing was outside the recognised therapeutic standard and that he had failed to:

- take adequate histories, conduct examinations or otherwise properly assess the appropriateness of his prescribing for these patients considering their histories, conditions, and contraindications
- adequately disclose risks or explain that treatment was experimental, so that patients could provide informed consent
- liaise with the patients' treating GPs or psychiatrists
- seek required authorities to prescribe S8 medication for longer than two months
- provide adequate supervision or follow up when prescribing doses for patients
- use clinical judgement and consider the possibility of accidental or deliberate misuse when prescribing for self-administration
- provide patients with appropriate contact information in case of any difficulties or concerns with treatment.

[1]As at the date of publication of this case study, the Therapeutic Goods Administration has only approved esketamine nasal spray (Spravato) for treatment resistant depression. Other than this, the use of ketamine to treat depression has not been approved by the TGA. The Royal Australian and New Zealand College of Psychiatrists published a clinical memorandum in July 2022 on the use of ketamine in psychiatric practice

Medical records

It was also alleged Dr C's records were inadequate and that he failed to document the patients' history or information relevant to his examinations, assessment, diagnosis, clinical opinion, medication list, treatment plan, advice or information provided to the patient. Nor did he keep notes of the patients' progress at each visit.

Expert opinion was critical of the inadequacy and illegibility of the records.

Insurance

It emerged at the hearing that Dr C did not have appropriate insurance to practise other than as a CMO.

Outcome

The tribunal concluded Dr C's conduct constituted professional misconduct.

Dr C's registration was immediately suspended following the initial hearing.

At the penalty hearing, the tribunal was particularly concerned about Dr C's apparent lack of insight into the potential harm to his patients. He appeared not to take responsibility for his actions, nor did he seem to recognise he lacked relevant skills or experience necessary to prescribe ketamine safely. He had not taken any courses or education to address the deficits in his knowledge.

His registration was cancelled for two years. He was ordered to pay costs.

Key lessons

Ensure there is sufficient clinical justification for any medication you are prescribing.

Only prescribe where you have enough information about the patient's past medical history and current medical conditions and medications to satisfy yourself the prescription is appropriate and not contraindicated.

You should take into account any advice from entities such as the TGA and any relevant clinical guidance.

You should discuss the risk-benefit profile of the medication, inform the patient whether the treatment is recognised or unusual, or 'off-label' and what that means. You need to satisfy yourself the patient understands this information and can provide informed consent to treatment. Keep careful records of any information you provide the patient about the treatment.

If prescribing is experimental and not supported by a reasonable evidence base, it should only be used within an approved clinical trial.

Make sure you understand your legal responsibilities when prescribing drugs of dependence. This includes seeking appropriate authorities for prescribing and checking real-time monitoring or drug-dependent patient registers where required.

When you prescribe medications, you are responsible for making appropriate arrangements to follow the progress of the patient or manage adverse events and report any adverse reactions to the TGA.

You are obliged to communicate clearly and effectively with other practitioners caring for the patient, keep them informed and co-ordinate care.

Maintain records of your consultations that would enable another practitioner to take over care of the patient. This includes information about the patient's history, examination and test results, diagnosis, medications prescribed, outcomes of the treatment and the ongoing treatment plan.

Recognise and work within the limits of your competence and scope of practice and ensure you have adequate knowledge and skills to provide safe clinical care.

Ensure you have appropriate insurance for all the work you do.

References and further reading

Avant factsheet – Prescribing drugs of dependence

Avant eLearning – Prescribing principles: Chapter one – general prescribing issues

Avant eLearning – Prescribing principles: Chapter two – opioids and other drugs of dependence

Avant factsheet – Medical records: the essentials

Avant article – New and innovative procedures and consent

AJGP article – RACGP – Off label medicine use

For more information or immediate medico-legal advice, call us on 1800 128 268, 24/7 in emergencies.
avant.org.au/mlas

avant.org.au/avant-learning-centre