

Health insights

A reminder for pharmacists of the need to exercise caution when dispensing Schedule 3 Poisons

The case scenario

A complaint was made to the Pharmacy Board of Australia ('Board') that a pharmacist provided an excessive quantity of Restavit, a Schedule 3 poison, and for a duration for which there was no established therapeutic need. The pharmacist explained to the Board that he had supplied the drug as he believed it was clinically appropriate to do so, on the basis that the patient had reported experiencing symptoms of sleeplessness.

The Board's decision

The Board found that the pharmacist's performance was unsatisfactory as his actions were not in accordance with the Board's Guidelines on Practice-Specific Issues. Specifically, that he failed to take appropriate steps to discuss the excessive supply with the patient's GP and found that there were ineffective or insufficient systems in place at the pharmacy to monitor, and prevent, patients from being supplied excessive quantities of Schedule 3 poison without intervention.

As such, the Board decided to:

- Caution the pharmacist to ensure that he supplies Schedule 3 poisons to patient appropriately, including that he is satisfied of a therapeutic need for the supply and only supplying one proprietary pack at a time;
- Impose conditions on the pharmacist's registration, including that he undertake to successfully complete a program of education, and;
- Refer the matter to the Drugs and Poisons Regulation Group, given that the matter involved potential breaches of the Drugs and Poisons legislation.

Lessons to be learned

Pharmacists have a professional and legislative responsibility to ensure medicines are supplied lawfully and those medicines are safe and appropriate for the patient. The pharmacist must communicate with the prescribing doctor where there is reason to believe the dispensing of the medication may be unsafe, inappropriate or unlawful.

Pharmacy Guidelines on Practice-Specific Issues ('Guidelines')

Guideline 4 of the Guidelines outlines that all pharmacy staff need to be trained to ask specific questions of intending purchasers of Schedule 2 and 3 poisons, and



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that the pharmacist must be satisfied that there is a therapeutic need for the supply of that medication. The Guidelines state that a therapeutic need is not merely established by agreeing to supply the medicine on request, asking patients if they have used the medicine previously, or if they know how to use it.

Further, only one package of either a Schedule 2 or 3 poison is to be supplied at a time, unless there are exceptional circumstances. Caution should always be exercised when considering requests for supply of multiple packages, particularly for drugs subject to abuse or misuse.

Drugs, Poisons and Controlled Substances Regulations 2017 (‘Regulations’)

The Board referred the matter to the Drugs and Poisons Regulation Group because it took the view that the pharmacist may have breached the Regulations, which govern the supply of Schedule 3 poisons.

The Regulations mirror the above Guidelines in that a pharmacist must not sell, supply or administer a Schedule 3 poison unless the pharmacist has taken all reasonable steps to ensure a therapeutic need exists for that poison (S 141). Other restrictions include ensuring that Schedule 3 poisons are not stored in a way that promotes the sale of that poison or draws undue attention to it (S 143).

Penalties

A breach of the Guidelines can result in a finding by the Pharmacy Board of Australia of unprofessional conduct, whilst a breach of the Regulations can carry significant monetary penalties for the pharmacist concerned. For example, if a pharmacist has not taken all reasonable steps to ensure a therapeutic need exists for the poison, he or she may face a fine in excess of \$7,000.

It is important for practitioners to be aware of, understand, and act in accordance with these Regulations and Guidelines, which are aimed at facilitating and enhancing the appropriate supply of controlled medications. Owners of pharmacies must understand their legal obligations, given that action may be taken for breaches that occur in their pharmacy, even without their direct involvement.

THIS ARTICLE WAS WRITTEN BY PRINCIPAL KELLIE DELL'ORO, SOLICITOR ZALMAN BASSIN AND PARALEGAL LLOYD HUTSON OF MERIDIAN LAWYERS. PLEASE CONTACT US IF YOU HAVE ANY QUESTIONS.

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