Medicolegal Considerations When Prescribing Compounded Medications

Reading time:
Owen Bradfield
Date created: 24/06/2024

Background

Although listed on the Pharmaceutical Benefits Scheme for the medical management of Type 2 Diabetes Mellitus, Semaglutide has been shown to induce weight loss in individuals without diabetes. Its popularity as a weight loss drug has led to widespread shortages of commercially available Semaglutide and increased consumer demand for compounded replicas. This has led to some companies compounding Semaglutide on a large scale.

In May 2024, a Four Corners Investigation uncovered concerns around the safety of compounded Semaglutide amidst growing concerns about patient side effects and the uncontrolled environments in which they are compounded. In response, the Federal Government will ban the compounding of Semaglutide from 1 October 2024.

Under the Therapeutic Good Act 1989 (Cth) and the Therapeutic Goods Regulations, medications can only be lawfully compounded for a specifically-named patient. They cannot be compounded in bulk for future patient demand. The Therapeutic Goods Administration has executed warrants and seized compounded medications from pharmacies breaching these legal obligations. Ahpra has also indicated that it will focus regulatory attention on doctors who are exploiting patient demand for compounded medications such as Semaglutide.

These recent developments provide an opportunity to discuss some of the medicolegal considerations when prescribing any compounded medication, not just Semaglutide.

Medicolegal considerations

First, compounded medicines are not required to be manufactured in a licensed or approved facility that is regulated by the TGA, which means there are fewer safety and quality controls. Therefore, compounded medicines should be prescribed with caution, such as where an appropriate commercially available product is clinically unsuitable. This might occur if the patient is allergic to a component in the commercial product, or the patient requires the medication in a form that allows for a different route of administration.

Second, prescribers should ensure, when prescribing a compounded medicine, that patients have been provided with information about the medicine which has been prescribed for compounding, and that they understand that compounded medicines are not assessed by the TGA for efficacy, quality, and safety.

Third, if a compounded medicine is being considered, the prescriber should clearly document in the clinical record: 1) why a compounded alternative has been prescribed and why a commercial product is considered unsuitable; and 2) any information provided to patients about why a commercial product is considered unsuitable and the safety and quality control limitations of compounded medicines; and 3) the patient's consent (or refusal to consent) to the prescription and use of a compounded alternative.

Fourth, prescribers should avoid "channelling" patients to a particular pharmacy to obtain compounded alternatives to commercial medicines that are available and suitable. The Medical Council of NSW has previously taken regulatory action by imposing restrictions on a practitioner's registration in similar circumstances.

Key takeaways

1. Prescribe compounded medicines cautiously, such as when commercially available products are unsuitable.
2. Inform patients about the lack of safety and quality data for compounded replicas.
3. Document your discussions with patients in the clinical record.

making with regard to the individual circumstances. Information is only current at the date initially published. If in doubt, contact our claims and 24-hour medico-legal advice and support team on 1300 698 573. You should consider the appropriateness of the information and read the Member Handbook Combined PDS and FSG before making a decision on whether to join MIPS.