



Pharmacy Board of Australia and Medical Board of Australia

24 November 2017

Joint statement on compounded medicines

The Pharmacy Board of Australia and Medical Board of Australia remind medical practitioners and pharmacists about their respective responsibilities in the prescribing and dispensing of compounded medicines.

Good practice involves effective communication between medical practitioners prescribing and pharmacists dispensing prescribed medicines. It also involves an understanding of the important role of each profession to ensure that the interests of the patient are their primary priority.

The issue

A compounded medicine may be a suitable treatment option for some patients. For example, if a patient:

- has an allergy or sensitivity to an excipient (such as a preservative) in the commercial product (i.e. ready prepared product), or
- requires a different dose form to the commercial product, such as for a patient who has difficulty swallowing.

Unlike medicines on the Australian Register of Therapeutic Goods (ARTG), compounded medicines are not subject to rigorous assessment for product efficacy, quality and safety by the Therapeutic Goods Administration (TGA), and therefore additional considerations are required.

Good practice

1. A compounded medicine should only be prescribed by a medical practitioner and prepared by a pharmacist where it is clinically indicated and if:
 - an appropriate commercial product is unavailable, or
 - a commercial product is unsuitable.
2. As is the case for any commercial product, when prescribing and compounding a medicine, medical practitioners and pharmacists must know and comply with the requirements of their state or territory drugs and poisons (or equivalent) legislation, and consider any relevant practice standards and guidelines.
3. Medical practitioners and pharmacists have individual legal and professional responsibilities when a compounded medicine is prescribed and subsequently compounded and dispensed. They have responsibilities to:
 - 3.1 assess whether the compounded medicine is safe and appropriate for the patient. This includes considering:
 - whether the substance(s) in the compounded medicine are suitable and approved for human use

- whether there is sufficient evidence to support the intended use based on recognised therapeutic standards
- whether the medicine will remain stable for the duration of use, and
- the possibility of contamination of the medicine and the level of risk that contamination would present. An example is the risk of contamination of injections and eye drops that should be sterile

3.2 consider the need for any specialised equipment required to compound the medicine

3.3 support patients to make an informed decision about their treatment by ensuring that they:

- have been provided with information about the medicine which has been prescribed for compounding, and
 - understand that unlike medicines on the ARTG, compounded medicines have not been assessed by the TGA for efficacy, quality and safety.
4. A pharmacist who receives a request to prepare a compounded medicine for which there is a close formulation to a suitable medicine on the ARTG and which is unlikely to produce a different therapeutic outcome to the ARTG medicine should consult with the prescribing medical practitioner regarding alternative treatment options¹.
 5. If a pharmacist believes that it is not safe or appropriate to compound a prescribed medicine, they must communicate their concerns to the prescriber and patient so that alternative options can be considered. This may include not compounding the prescribed medicine and recommending another suitable medicine.

The Pharmacy Board of Australia has issued *Guidelines on compounding of medicines* for pharmacists, which are published on its [website](#).

¹ An example is an order for 450mg amoxicillin capsules instead of the commercially available 500mg capsules.