

Frequently asked questions

For pharmacists applying the Pharmacy Board of Australia's Guidelines on compounding of medicines

September 2024

The Pharmacy Board of Australia (the Board) has developed these frequently asked questions (FAQs) to provide pharmacists with additional information and clarification on a range of issues relating to its guidance on the compounding of medicines by pharmacists as set out in the *Guidelines on compounding of medicines*.

Therapeutic goods legislation

The <u>Therapeutic Goods Regulations 1990</u>¹ provide the following exemptions relevant to pharmacists in relation to the extemporaneous preparation (compounding) of medicines for human use:

a. Australian Register of Therapeutic Goods (ARTG):

Compounded medicines (other than medicines that are used for gene therapy, that are medicinal cannabis products or that contain glucagon-like peptide-1 (GLP-1) receptor agonist analogues) are not required to be entered on the ARTG before they can be supplied, provided they are extemporaneously compounded by a pharmacist for a particular person, for therapeutic application to that person.

Medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) that are compounded in a hospital in anticipation of being needed for therapeutic application to patients of the hospital are not required to be entered on the ARTG provided they are considered by the hospital's drug and therapeutic committee to be appropriate for compounding in anticipation of being needed to treat the patient.

b. Manufacturing of medicines:

A licence from the TGA is not required when a pharmacist is:

- i. Practising:
 - in a pharmacy that is open to the public, or
 - on the premises of a private hospital.

(Note: supply must be on or from those premises and must not be by wholesale).

OR

ii. Employed in public hospitals or public institutions, and medicines are manufactured for supply in public hospitals or public institutions in the same state or territory.

About these FAQs

These FAQs should be considered in conjunction with:

- relevant legislation
- practice standards

¹ Available at <u>www.comlaw.gov.au/Series/F1996B00406</u>

- the Australian Pharmaceutical Formulary and Handbook
- the Board's Guidelines on compounding of medicines
- · any other documents referred to in the guidelines, and
- the Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists published by the Board.

Clarification in relation to state, territory and Commonwealth requirements including the Therapeutic Goods Administration's (TGA's) regulatory requirements should be sought from the relevant entity. TGA has published GMP information for manufacturers of compounded medicines and DAAs - Including information about the supply of medicines by community pharmacists which may be helpful. The Board is unable to provide advice on requirements set by other entities.

Each individual set of circumstances may not be fully covered in these FAQs and readers should not make commercial decisions based on the information contained in these FAQs without first seeking independent advice.

These FAQs will be reviewed and updated as required to incorporate any additional information that may further clarify the Board's *Guidelines on compounding of medicines*, referred to in this document as the Guidelines. When referring to other guidelines published by the Board the full title of the other guidelines will be used.

Frequently asked questions

1. As a pharmacist, can I prepare compounded medicines in anticipation of receiving prescriptions for these medicines?

The exemptions allowing pharmacists to compound medicines are based on pharmacists compounding for a particular person. You are not permitted to store excess quantities of compounded medicines in case additional prescriptions are subsequently presented by patients. This contrasts with:

- a pharmacist working in premises that hold a manufacturing licence from the TGA who are permitted to compound medicines in advance of receiving prescriptions or orders
- a pharmacist working in a hospital who is permitted to compound a medicine in anticipation of being
 needed for therapeutic application to patients of the hospital, where the medicine is considered by the
 hospital's drug and therapeutic committee to be appropriate for compounding in anticipation of being
 needed to treat the patient.
- 2. As a pharmacist, how should I deal with a request from a health practitioner or veterinary practitioner, authorised to prescribe scheduled medicines under state or territory legislation, to supply them with compounded medicines for use in their surgery/clinic/treatment room or other location where they practise?

There are three alternatives that may apply:

- a. If practising in a jurisdiction where compounding is only permitted upon presentation of a prescription for a human, or instructions from a veterinary practitioner for an animal you must comply with this requirement.
- b. The *Therapeutic Goods Regulations 1990* contain an exemption from the requirement for a medicine to be included in the Australian Register of Therapeutic Goods where the medicine is extemporaneously compounded for a particular person for therapeutic application to that person. If you are relying on this exemption, before supplying a medicine to an authorised prescriber for use in their surgical/clinic/treatment room, you should ensure that the medicine is for an individual patient.

c. There are circumstances where the *Therapeutic Goods Act 1989* and Regulations do not apply and where the applicable state or territory legislation allows the supply.

Compounding medicines in any of the above circumstances may give rise to requests for compounding on a large-scale. There are inherent risks in compounding medicines on a large scale, which in the absence of strict processes and procedures followed in licensed premises by manufacturers (such as testing of medicines and registration of medicines), has the potential to adversely affect patients.

Further information about licensing of premises is available from the <u>TGA website</u>. Further information about the regulation of veterinary medicines is available from the <u>APVMA website</u>.

If you have queries about the requirements that apply in your state or territory you should contact the relevant authority that is responsible for administering drugs, poisons and controlled substances legislation or other relevant legislation. Further information about contacts for state or territory drugs and poisons units is available from the TGA website.

Refer to the following guidance in the Guidelines:

- Guideline 1: When to compound medicines
- Guideline 5.2: Quantity to be supplied
- Guideline 7: Batch preparation
- 3. As a pharmacist, can I supply compounded medicines to a veterinary practitioner for their use in the course of the treatment of their patients?

A veterinary practitioner would be required to provide instruction to you to compound medicines that are of sufficient quantity for the particular animal(s) to be treated. The Australian Veterinary Association has developed and published The Australian Veterinary Association (AVA) Guidelines for the Preparation and use of Compounded Pharmaceuticals, which contains further information.

Relevant legislation may also set out requirements for the supply of compounded medicines to a veterinarian. If you have queries about the requirements that apply in your state or territory you should refer to the relevant legislation or contact the relevant authority that is responsible for administering the legislation.

4. I am a pharmacist practising in a community pharmacy that does not hold a manufacturing licence from the TGA. Can I prepare a batch of compounded medicines?

A manufacturing licence from the TGA is not required for you to compound multiple units of issue of a particular product (i.e. a batch), provided the batch is compounded in accordance with legislation, for example, you have a prescription or order for individual named patients unless exempt in legislation.

Guideline 7 of the Guidelines provides guidance about considering the risks associated with batch preparation.

Also refer to question 13 regarding the compounding of a batch of injections.

5. I am a pharmacist practising in a compounding pharmacy that does not hold a licence from the TGA. If I am asked to supply a compounded medicine to a patient by mail or courier can I instead arrange for it to be picked up at the patient's local pharmacy if agreed by the patient (e.g. for the patient's convenience or to maintain the cold chain)?

In this case, you are the 'compounding pharmacist' as well as the 'dispensing pharmacist', and would be responsible for dispensing, compounding, recording and counselling of the patient on the compounded medicine. You are also responsible for ensuring that the medicine is safely received by the patient.

With the patient's consent you could seek the assistance of the pharmacist at the patient's local pharmacy to help deliver the medicine to the patient. You would need to confirm with the pharmacist that

you have contacted the patient and have provided counselling and information about how to collect the compounded medicine. The Board's guidance on indirect supply contained in the <u>Guidelines for</u> dispensing of medicines must also be adhered to.

6. What should I do if I receive a prescription for a compounded medicine, but I do not think that I will be able to compound the prescribed medicine to the required standard?

If you do not have the required competencies and/or equipment to safely compound a medicine to the required standard which will be safe to use, then you should not compound the medicine and advise the patient that they will need to take their prescription to a different pharmacy.

The consumer fact sheet <u>published</u> by the Board may be useful to support communication with the patient.

Refer to the following guidance in the Guidelines:

- Guideline 2: Competence to undertake compounding
- Guideline 4: Facilities, equipment, working environments, materials and support staff
- 7. What process should I follow to become competent in complex compounding?
 - Identify the competencies to be achieved which are relevant to the areas of complex compounding (e.g. aseptic compounding) to be carried out and develop your individualised practice profile (refer to the section 'Creating an individualised professional practice profile' in the National Competency Standards Framework for Pharmacists in Australia, 2016).
 - Identify CPD needs relevant to the identified competencies and document these in the form of a CPD plan.
 - Identify and undertake CPD activities (including a training program) that address the identified CPD needs.
 - Gain experience, until competence is achieved, in premises that are adequately designed, equipped, maintained and approved by relevant authorities. For example, a compounding pharmacy or a hospital pharmacy department.

You are reminded that if you are unable to achieve competence to undertake a specific task/activity (for reasons such as unavailability of suitable training), you should not undertake this task/activity unsupervised until competence is achieved.

Refer to Guideline 2: Competence to undertake compounding of the Guidelines.

8. Should every pharmacist who works in the area of compounding have the same level of training and/or experience? If I mentor or supervise other pharmacists in compounding, or if I oversee a compounding service, will I require additional training and/or experience?

It is up to each individual pharmacist to ensure they meet the Board's annual CPD requirements, taking into consideration their individual scope of practice. Every pharmacist is expected to plan their annual CPD by reflecting on the role they perform and services they provide (i.e. their scope of practice), and identify professional development needs relevant to the identified competencies. This means that individual pharmacists may vary in their scope of practice and therefore the training course(s) they complete and the experience they gain.

If you mentor or supervise other pharmacists in the area of compounding you would have a different scope of practice to the pharmacists you supervise, and would require different competencies and/or be required to practise at a different performance level to act in this role. Your training and/or experience should address these competencies, for example those addressed under 'Supervise personnel' in the National Competency Standards Framework for Pharmacists in Australia, 2016.

If you oversee a compounding service, you would also require different competencies compared to the other pharmacists practising in the facility. This may include competencies from the Leadership and management domain of the National Framework.

9. Can a dispensary assistant/dispensary technician or hospital pharmacy technician compound medicines?

Yes. Trained dispensary assistants/dispensary technicians or hospital pharmacy technicians may be involved in simple and/or complex compounding, provided they are suitably trained and experienced to perform the specific tasks carried out, and they are working under the direct supervision of a pharmacist.

The support by these individuals should be in accordance with the guidance in Guideline 12: Dispensary assistants/dispensary technicians and hospital pharmacy technicians of the Board's *Guidelines for dispensing of medicines*. The pharmacist supervising the compounding bears the ultimate responsibility for the product being compounded.

Refer to Guideline 4.3: Supervision of support staff of the Guidelines.

10. Can an aseptic compounding service be provided outside of a public hospital pharmacy setting?

Yes. Competence to compound such products, while also ensuring appropriate processes are followed and equipment and facilities are used, is crucial to the provision of such services to the public.

Refer to the following guidance in the Guidelines:

- Guideline 2: Competence to undertake compounding
- Guideline 4: Facilities, equipment, working environments, materials and support staff
- 11. Under Guideline 3.1: Sterile medicines, the guidance outlines that I am expected to comply with the principles outlined in one of the following compounding guides/standards:
 - the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010), or
 - the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 0092), or
 - the USP-NF (797) Pharmaceutical Compounding—Sterile Preparations.

Where can I access these documents?

Pharmacists are responsible for accessing the relevant document(s) and where relevant, any costs for access. The following websites should be reviewed:

- www.picscheme.org/
- www.tga.gov.au/publication/manufacturing-principles-medicinal-products
- www.usp.org/usp-healthcare-professionals/compounding
- 12. In complying with the guidance under Guideline 3.1: Sterile medicines can I follow the principles from a combination of the listed guides/standards, or do I have to pick the one that is most relevant to my practice and adhere to that?

The guidance advises pharmacists to choose one of the following guides/standards, whichever is the most appropriate and relevant to their compounding practice, and follow the principles from:

- the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010), or
- the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009), or

²The current version adopted by the TGA is specified under the Therapeutic Goods (Manufacturing Principles) at www.tga.gov.au/publication/manufacturing-principles-medicinal-products.

• the USP-NF (797) Pharmaceutical Compounding—Sterile Preparations.

If a pharmacist modifies any of the principles from the guide/standard being followed, the following factors could be considered (e.g. by the Board, an auditor or other decision maker) in relation to the pharmacist's actions:

- Was the action reasonable?
- Was it based on a documented risk assessment?
- Was patient safety compromised as a result?
- Was product quality, safety and efficacy compromised as a result?

13. Can I compound and supply a batch of injections to a particular patient?

Compounding of batches is addressed in the full set of compounding guidelines under Guideline 7 Batch preparation, and in question 4 above.

The exemptions provided for in therapeutic goods legislation which allow pharmacists to compound medicines allow pharmacists to compound a medicine for a particular person and do not limit batch size.

Provided the appropriate guidance is followed in assigning a longer expiry date (such as for a week's supply), and the pharmacist has an order for the compounded medicines for the particular patient, this would be in accordance with the Board's guidelines and the therapeutic goods exemptions.

Pharmacists are reminded of their responsibility to provide appropriate advice and information to others who are responsible for administration of the compounded injectable medicine, on what is acceptable to support the proper use of the medicine. This could include the period of time over which an injection or infusion should administered, and when the medicine should be discarded.

14. If I am involved in compounding veterinary products, or would like to become involved in compounding veterinary products, what other information is available to me?

The Australian Veterinary Association has developed and published the policy <u>Veterinary use of compounded pharmaceuticals</u> (1 Dec 2020) as well as <u>Guidelines for the preparation and use of compounded pharmaceuticals (2020)</u>, which contain guidance for veterinary practitioners on the use of compounded medicines in veterinary practice. Although these guidelines technically do not apply to pharmacists, they may provide you with some useful information and considerations in veterinary compounding.

Refer to Guideline 15: Reference texts and other sources of information relevant to compounding of the Guidelines.

15. I have received a prescription for a compounded veterinary medicine that is only slightly different to a commercial product. Can I compound the medicine?

The guidance (Guideline 1.1.1: The availability of a commercial medicine) states that a pharmacist must not compound a slightly different medicine that is unlikely to produce a different therapeutic outcome. When compounding veterinary medicines, the dosage will need to be appropriate for the animal species being treated. In some cases this may only require a small change in strength, a change for palatability enhancement or different formulation or dosage type to facilitate administration. If the commercial product is not suitable for the patient for reasons such as dosage, formulation, flavouring or method of administration, compounding can be considered.

16. Does the Board provide training on how to comply with the relevant practice standards and guidelines?

No, provision of training to pharmacists is not within the Board's functions.

If pharmacists feel they need assistance in ensuring they are able to comply with the relevant practice standards and guidelines, including the guides/standard listed in the guidance, they should consider contracting or employing a suitable person to assist in the self-assessment and audit of their

compounding practice. This person may be able to provide advice on any required training, including how the training can be accessed.

A list of regulatory affairs consultants can be found at http://www.tga.gov.au/regulatory-affairs-consultants.

Refer to the following guidance in the Guidelines:

- Guideline 2: Competence to undertake compounding
- Guideline 3.2: Self-assessment and audit

17. Do I need a third party assessor and how can I find one?

Pharmacists need to be able to assure themselves that they are meeting the required standard through a self-audit.

As part of the risk management processes for compounding medicines in the pharmacy in which they practise, pharmacists can consider contracting or employing a suitable person to assist with their self-assessment and audit against the standards.

Although audit by a third party has not been mandated by the Board in its guidance, it is a resource available to all pharmacists and may be a useful tool given the variation in the regulation affecting pharmacy premises in different jurisdictions.

A list of regulatory affairs consultants can be found at http://www.tga.gov.au/regulatory-affairs-consultants. These consultants may be able to audit against a range of standards.

Refer to Guideline 3.2: Self-assessment and audit of the Guidelines.

18. Who would be an 'authorised entity' that could conduct an independent audit of compliance with legislation, guidelines and practice standards, as referred to in the guidance (Guideline 3)?

A jurisdictional health department or the relevant state/territory pharmacy premises regulatory authority or responsible body, could be an 'authorised entity' to conduct an audit of compliance in a jurisdiction.

The Board notes there may be variation in the type and schedule of audits conducted by authorised entities and variation in the regulation of pharmacy premises across jurisdictions. Information about such audits should be obtained directly from the authorised entities.

19. Does the Board provide specific guidance or advice on designing compounding facilities?

The Board does not provide specific guidance on how to comply with facility design requirements (such as for cleanrooms, isolators and biological safety cabinets).

The section, Relevant legislation, quality standards and practice standards, of the Guidelines states that the guidelines must be read in conjunction with a number of resources which address facility design, including:

- codes and guidelines published by jurisdictional pharmacy premises regulatory authorities about pharmacy premises
- Australian standards for clean rooms, and
- SHPA practice standards.

To ensure that these requirements are being met, particularly if there are any discrepancies between any of the relevant standards, pharmacists should contact relevant entities. This may include the local health department, state or territory pharmacy premises regulatory authorities, and/or other responsible bodies for advice.

20. If I am undertaking complex compounding (e.g. sterile injectable medicines), do I need additional PII cover?

The Introduction reminds pharmacists that compounding practices must be covered by professional indemnity insurance arrangements that comply with the Board's *Registration standard: Professional*

indemnity insurance arrangements. Pharmacists must check with their professional indemnity insurance (PII) provider, that their policy indemnifies their practice. This aligns with the Board's PII registration standard which requires pharmacists to conduct a self-assessment of their practice and seek expert insurance advice to ensure they have appropriate cover for their individual practice, taking into consideration the risks involved.

Abbreviations

ARTG Australian Register of Therapeutic Goods

APF Australian Pharmaceutical Formulary and Handbook

CPD Continuing professional development TGA Therapeutic Goods Administration