Frequently asked questions

For pharmacists on the compounding of medicines

16 January 2020

The Pharmacy Board of Australia (the Board) has developed these frequently asked questions (FAQ) to provide pharmacists with additional information and clarification on a range of issues relating to the compounding of medicines, including the compounding of sterile injectable medicines. These FAQ should be considered in conjunction with the Board's *Guidelines on compounding of medicines* (the guidelines), any documents referred to in the guidelines, and the *Background on the regulation of compounding by pharmacists* published by the Board.

These FAQ will be reviewed and updated as required to incorporate any additional information that may further clarify issues relevant to the compounding of medicines.

Information provided in relation to state, territory and Commonwealth requirements including the Therapeutic Goods Administration's (TGA's) regulatory requirements is provided as a guide only. 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.

Frequently asked questions

1. **The Board's guidelines use the terms 'commercial product' and 'commercially available'. How should I interpret these terms?**

   For the purposes of the Board's guidelines, 'commercial product' and 'commercially available' refer to medicines that are listed on the Australian Register of Therapeutic Goods (ARTG) that are able to be accessed by pharmacists via a wholesaler or directly from the manufacturer.

2. **I practise in a community pharmacy. What am I able to compound for patients?**

   As a pharmacist working in a community pharmacy you are able to compound and supply from that community pharmacy a medicine that:

   - is a Schedule 4 or Schedule 8 medicine when a prescription has been received for a particular person, or
   - is a Schedule 2, Schedule 3 or unscheduled medicine when a particular person requests such a medicine, and

   it is not a medicine that:

   - is used for gene therapy.

   Medicines compounded in these circumstances are not required to be entered on the Australian Register of Therapeutic Goods (ARTG). The community pharmacy you are practising at does not need to hold a manufacturing licence from the Therapeutic Goods Administration (TGA) unless medicines are:

   - biological, or
   - compounded for the purpose of supplying by wholesale (e.g. to sell to another pharmacy).

If you are practising in a community pharmacy that provides services to a private hospital you may compound medicines for particular persons as outlined above.

(Note:

i. This provides for both simple and complex compounded medicines.

ii. In the case of a compounded veterinary medicine, instruction is required from a veterinary surgeon/practitioner regardless of the schedule of the medicine to be compounded.)

iii In relation to gene therapy, the development and use of genetically modified organisms (GMOs) is controlled under the Gene Technology Act 2000 (the Act) and is administered by Office of the Gene Technology Regulator (OGTR). You will be required to obtain a license to use a genetically modified product in Australia from the Gene Technology Regulator. You may also wish to contact OGTR regarding regulatory requirements for clinical research involving gene therapy.

A clinical trial involving an unapproved therapeutic good (including gene therapy) is subject to the Therapeutic Goods Act 1990, including approval from and oversight by a Human Research Ethics Committee (HREC). Information on regulation of medicines produced by genetic manipulation.

Information on human genetic research ethical review processes can be found in Chapter 3.5 of the National Statement on Ethical Conduct in Human Research (published by the National Health and Medical Research Council (NHMRC).)

3. I practise in a private hospital pharmacy. What am I able to compound for patients?

See question 2.

4. I practise in a public hospital pharmacy department. What am I able to compound for patients?

As a pharmacist working in a public hospital pharmacy department, you are able to compound and supply a medicine that:

- is a Schedule 4 or Schedule 8 medicine, when a prescription has been received for a particular person, or
- is a Schedule 2, Schedule 3 or unscheduled medicine when a particular person requests such a medicine

and it is not a medicine that:

- is used for gene therapy.

Medicines compounded in these circumstances are not required to be entered on the ARTG. The pharmacy you are practising at does not need to hold a manufacturing licence from the TGA, unless the medicine is a biological.

As a pharmacist working in a public hospital pharmacy department you are also able to supply compounded medicines to other public hospitals or public institutions in the same state or territory.

(Note:

In relation to gene therapy, the development and use of genetically modified organisms (GMOs) is controlled under the Gene Technology Act 2000 (the Act) and is administered by Office of the Gene Technology Regulator (OGTR). You will be required to obtain a license to use a genetically modified product in Australia from the Gene Technology Regulator. You may also wish to contact OGTR regarding regulatory requirements for clinical research involving gene therapy.

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5. As a pharmacist, can I compound a non-prescription medicine (containing unscheduled, Schedule 2 or Schedule 3 ingredients) for general sale in the pharmacy (i.e. not for a specific patient)?

No. The *Therapeutic Goods Regulations* 1990 specify that a compounded medicine does not have to be entered on the ARTG if it is compounded by a pharmacist for a particular person, for therapeutic application to that person. If you wish to compound a non-prescription medicine for general sale in the pharmacy, the medicine will need to be entered on the ARTG. Unless they are exempt goods, it is illegal to supply medicines that are not included in the ARTG.

6. When is licensing of premises by the Therapeutic Goods Administration (TGA) required?

A manufacturing licence from the TGA is required if a pharmacist intends to compound biologicals, or compound medicines in a pharmacy and supply these by wholesale, for example to other pharmacies. In this case, if the compounded medicine is not for supply to an individual named patient (e.g. by way of a prescription or order), it would also need to be included in the ARTG. A manufacturing licence from the TGA is not required if medicines are compounded only on a prescription or order for, or on request by a particular person, for therapeutic application to that person, or on a request from an authorised prescriber for use in their surgical/clinic/treatment room for an individual named patient. Public hospital pharmacy departments do not require a manufacturing licence if they supply compounded medicines to other public hospitals or public institutions in the same state or territory.

7. Can I ask a pharmacist at a different pharmacy to compound a medicine which I would then obtain in order to dispense and supply it to a patient at the pharmacy where I practise?

If working in a community pharmacy or in a private hospital pharmacy you can obtain a compounded medicine from another pharmacy, if the other pharmacy holds a manufacturing licence from the TGA. If the compounded medicine is not for supply to an individual named patient (e.g. by way of a prescription or order), it would also need to be included in the ARTG. If the other pharmacy does not hold a manufacturing licence from the TGA, you would need to compound the medicine in the pharmacy where you practise, or advise the patient to take the prescription to another pharmacy to have the medicine compounded, dispensed and supplied.

If working in a public hospital pharmacy department you can obtain compounded medicines from other public hospitals in the same state or territory, or from a pharmacy that holds a manufacturing licence from the TGA.

8. I have obtained a compounded medicine from a pharmacy which holds a manufacturing licence from the TGA, in order to dispense and supply it to a patient. Who is responsible for ensuring the medicine arrives safely to the patient?

The ‘compounding pharmacist’ must ensure it is safely transported to the ‘dispensing pharmacist’.

As the ‘dispensing pharmacist’ who will be supplying the medicine to the patient, you are responsible for ensuring that the medicine arrives safely to the patient. This would include any transportation (e.g. by courier) that is required to get the medicine to the patient.

9. 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.

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 Guidelines for dispensing of medicines must also be adhered to.

10. As a pharmacist, how should I deal with a request from a prescriber, authorised under state or territory legislation, to supply them with compounded medicines for use in their surgery/clinic/treatment room 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, 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. In circumstances where the *Therapeutic Goods Act* 1989 and Regulations do not apply and where the applicable state or territory legislation allows the supply, this should not result in large scale compounding given that compounding of medicines in such circumstances may not be subject to testing of products, as is required when medicines are manufactured in premises licensed by TGA. There are inherent risks in compounding medicines on a large scale, which in the absence of strict processes and procedures followed by licensed premises, has the potential to adversely affect patients. Supply in such circumstances must not be considered as an opportunity to avoid the stringent requirements applicable in manufacturing by licensed premises. Further information about licensing of premises is available from the TGA website.

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. Further information about contacts for state or territory drugs and poisons units is available from the TGA website.

11. As a pharmacist, can I supply compounded medicines to a veterinary surgeon for their use in the course of the treatment of their patients?

A veterinary surgeon 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.

12. 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?

As the pharmacist, it is your responsibility to ensure that any compounded medicine that you compound and supply to a patient is safe and appropriate for the patient. If you believe you will not be able to meet this professional obligation (e.g. because you do not have the required competencies and/or equipment), or you believe that supply by another compounding pharmacist would be in the patient's best interest, you should not compound the medicine and discuss this with the patient, advising them of other more appropriate options to obtain the medicine.

13. What are the differences and similarities between simple and complex compounding?

A number of differences and similarities between simple and complex compounding are outlined in the table below.

Issue for comparison	Simple compounding	Complex compounding
Involves special competencies, equipment, processes or facilities	No. Pharmacists entering the profession are competent to undertake simple compounding in premises using standard compounding equipment and facilities.	Yes. The guidelines provide guidance on the obligations of pharmacists in relation to competencies, equipment, processes and facilities.
Examples of compounded medicines	Products from formulations published in reputable references (e.g. APF). Products using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available and considered before compounding.	Sterile preparations, including eye drops and eye ointments. Preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxics or hormones). Micro-dose single-unit dosage forms containing less than 25mg (or up to 25 per cent by weight or volume) of active ingredient. Sustained-release or other modified-release preparations.
Examples of such compounded medicines may include veterinary medicines	Yes	Yes
Must be carried out in accordance with relevant professional practice standards, guidelines and legislation	Yes	Yes
Products compounded must meet quality standards set out in the *Therapeutic Goods Act* 1989 (Cth) (or equivalent)	Yes	Yes
Entry-level pharmacists have addressed the relevant competencies and are deemed competent to compound these products	Yes	Maybe, depending on the education and training received during the pharmacy program and internship, and whether competence has been demonstrated to compound particular complex compounded medicines.
Pharmacists should develop a practice profile	A pharmacist may choose to develop a practice profile to describe any aspect of their practice. For simple compounding, the competencies outlined in the *National competency standards framework* may	Yes. The *Professional practice profile for pharmacists undertaking complex compounding* can be adapted to reflect the pharmacist's specific role, position or services provided. This will assist pharmacists to

Issue for comparison	Simple compounding	Complex compounding
	provide sufficient detail of the competencies required.	determine the education and training that needs to be completed to demonstrate competence to undertake complex compounding.
Pharmacists should undertake a self-assessment against the competencies outlined in the Professional practice profile for pharmacists undertaking complex compounding	The *National competency standards framework* may provide sufficient detail of the competencies required and so can be used to undertake a self-assessment in order to develop a learning plan. If a practice profile for simple compounding has developed, then a pharmacist can use this to undertake a self-assessment in order to develop a learning plan.	The *Professional practice profile for pharmacists undertaking complex compounding* can be used to undertake a self-assessment. This will assist pharmacists to reflect on their specific role, position or services provided to determine the education and training that needs to be completed to demonstrate competence to undertake complex compounding.
Pharmacists compounding such products are required to undertake CPD to achieve and/or maintain competence in this area	Yes, if learning needs are identified relating to this practice.	Yes, if learning needs are identified relating to this practice.
A risk assessment process should be followed	Yes, pharmacists should follow procedures for risk assessment in the APF.	Yes, pharmacists should follow procedures for risk assessment in the APF, and this should routinely be documented.
Appropriately trained staff can assist with compounding such products	Yes	Yes

14. Do the requirements for complex compounding outlined in the Board's guidelines apply when these products are prepared infrequently by a particular pharmacist or at a particular pharmacy?

Yes. The definition for complex compounding in the Board's guidelines is based on product type, not on the quantity to be compounded or the frequency of compounding. If the product to be compounded fits into the definition of 'complex compounding' the requirements for complex compounding apply. These requirements do not just apply to 'large' compounding pharmacies or pharmacists who frequently undertake complex compounding.

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

Yes. 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 you:

- have a prescription or order for individual named patients for each of the units of issue to be compounded, or
- have received instructions from a veterinary surgeon to compound the batch of compounded medicine for a particular animal or a group of animals.

The Board's guidelines provide guidance about considering the risks associated with batch preparation.

Also refer to question 36 regarding the compounding of a batch of injections.

16. When do I have to keep batch records and/or a dispensing worksheet for medicines I compound?

The Board's guidelines state that pharmacists are required to document the preparation of compounded medicines in accordance with state, territory and Commonwealth legislation, practice standards and guidelines, and the information published in the section *Extemporaneous dispensing* in the APF. Whether a single product is being compounded, or a batch of products compounded for named patients, appropriate records must be kept.

17. As a pharmacist, can I prepare a batch of 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 is in contrast to 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.

18. 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.

19. What process should I follow to become competent in complex compounding?

As a pharmacist, to become competent in complex compounding you should take the following steps:

- Review the *Professional practice profile for pharmacists undertaking complex compounding* (practice profile) and conduct a self-assessment against the practice profile to identify the competencies to be achieved which are relevant to the areas of complex compounding to be carried out. This may result in an individualised practice profile for that pharmacist.
- Identification of CPD needs relevant to the identified competencies and documenting these in the form of a CPD plan.
- Identifying and undertaking CPD activities (including a training program) that address the identified CPD needs.
- Gaining 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 (e.g. due to unavailability of suitable training), you should not undertake this task/activity until competence is achieved.

20. What process should I follow to become competent in aseptic compounding?

As a pharmacist, to become competent in aseptic compounding you should follow the same process that is required for you to become competent in complex compounding (as outlined in question 19 above). If aseptic compounding is the only area of complex compounding you will undertake, your individualised

practice profile will articulate the specific competencies, elements, performance criteria and evidence examples relevant to aseptic compounding. The corresponding training required to become competent would, at a minimum, need to be specific to your individualised practice profile.

Several training courses in sterile manufacture exist which should be considered as part of the process of achieving competence in this type of complex compounding.

21. 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 to act in this role. Your required 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* (National Framework).

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 domain *Leadership and management* of the National Framework, which are broader than those encompassed in the *Professional practice profile for pharmacists undertaking complex compounding.*

22. 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 Australian Veterinary Association (AVA) Guidelines for the Preparation and use of Compounded Pharmaceuticals, which contain guidance for veterinary surgeons 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.

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

Yes. Guidance in the Board's guidelines should be followed (noting that the section *Guidance on the compounding of sterile injectable* medicines applies from 1 February 2018). 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.

Guidance on the compounding of sterile injectable medicines

The following additional FAQ relate to the section *Compounding of sterile injectable medicines*, which was published on 1 August 2017 with an implementation date of 1 February 2018.

24. Is reconstituting an injection for a patient the same as 'compounding'?

Not for the purposes of the guidelines, as addressed in the section *Manipulation of products in accordance with manufacturer's instructions* of the guidelines. This section states that if a pharmacist is required to manipulate a commercially available product to produce a medicine in a 'ready to administer' form, if this is done in accordance with the manufacturer's instructions (including assigning of the 'in use expiry' and/or BUD), then this is not considered compounding.

25. What types of preparations does the guidance *Compounding of sterile injectable medicines* apply to?

The guidance applies specifically to the compounding of sterile injectable medicines, and lists the following types of preparations that it applies to:

- injections
- infusions
- concentrates for injections or infusions
- powders for reconstitution for injections or infusions, and
- gels for injections.

As a subcutaneous implant is an injection, the guidance applies to this type of preparation.

The guidance does not apply to sterile medicines that are not injectable, such as eye drops, eye ointments, irrigations and inhalations.

However, as stated in the section *Relevant legislation and practice standards* of the guidelines, a number of other relevant documents apply when a pharmacist compounds any medicine, including sterile medicines that are not injectable. When pharmacists compound these medicines, they need to ensure that all relevant legislation and practice standards and guidelines are met.

26. Under *Compliance with legislation, guidelines and practice* standards, the guidance outlines that I am expected to comply with the principles and procedures outlined in one of the following compounding guides/standard:

- **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[1]), or**
- **the USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations.**

Where can I access these standards?

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

27. Is Standard 5 *Compounding* in the Professional Practice Standards (PPS), relevant to me when I compound sterile injectable medicines?

As stated in the introductory text to the guidelines, the guidelines must be read in conjunction with Standard 5 *Compounding* of the Professional Practice Standards.

It is useful for a pharmacist to follow Standard 5 *Compounding*, however, following that standard alone cannot assure a pharmacist that they are compliant with the principles and procedures outlined in the guide/standard chosen for their overall compounding of sterile injectable medicines.

28. 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 a pharmacist feels 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

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

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.

29. 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.

30. 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?

A jurisdictional health department or the relevant state/territory pharmacy premises regulatory authority (PPRA) or responsible body, could be an 'authorised entity' to conduct an audit of compliance in a jurisdiction. TGA would only audit pharmacies that hold a manufacturing licence from the TGA.

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.

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

The section *Relevant legislation 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
- Several SHPA guidelines.

The Board does not provide specific guidance on how to comply with faculty design requirements (e.g. on cleanrooms, isolators and biological safety cabinets).

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 which may include the local health department and/or state/territory pharmacy premises regulatory authority (PPRA) and/or other responsible body for advice.

32. In complying with the guidance under *Compliance with legislation, guidelines and practice standards*, can I follow the principles and procedures in a combination of the listed guides/standard, 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/standard, whichever is the most appropriate and relevant to their compounding practice, and to adhere to that:

- 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
- the USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations.

If a pharmacist chose to modify some of the principles, processes and procedures to those in one of the other listed guides/standard, 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?

33. I am following one of the PIC/S Guides rather than USP–797 for my overall compounding practice and note that the Board's guidance states to follow the USP–797 to assign a BUD longer than 24 hours. In order to assign a BUD of > 24 hours, can I follow the principles and procedures in the PIC/S Guide I am following for my overall compounding practice instead of those outlined in USP–797?

In assigning a BUD of > 24 hours, the Board's guidance outlines that this would need to be in accordance with the requirements in the USP–797.

The Board's guidance also outlines that if a pharmacist chooses to follow guidance provided in a different guide or standard (which could include the guide used for the overall compounding of sterile injectable medicines), this may be acceptable, provided there is documented evidence that an equivalent or superior outcome has been achieved (i.e. that the compounded medicine will remain physically, chemically and microbiologically stable when stored under the specified storage conditions during the assigned BUD, and during the administration of the medicine to the patient).

34. What evidence, documentation or testing is required in order to assign a BUD of > 24 hours?

The Board's guidance requires pharmacists to only assign a BUD of > 24 hours if this is done in accordance with the guidance in USP–797. This would include any required testing of products or any other required evidence, as specified in USP–797.

If a pharmacist chooses to follow guidance provided in a standard other than the USP–797 in assigning an extended BUD, the onus would be on the pharmacist to document evidence that an equivalent or superior outcome has been achieved (i.e. that the compounded medicine will remain physically, chemically and microbiologically stable when stored under the specified storage conditions during the assigned BUD, and during the administration of the medicine to the patient). This would include any additional documentation and/or testing that was required.

35. How does the assigned BUD relate to the administration of the compounded sterile injectable medicine to the patient?

The guidance states that in assigning a BUD, pharmacists should take into account the intended commencement time of administration of the medicine to the patient. Effectively, this means that administration of the injection to the patient should commence within the assigned BUD.

Pharmacists are responsible for providing 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 (e.g. the period of time over which an injection or infusion should administered, and when the medicine should be discarded).

36. 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 *Batch preparation*, and in questions 15 to 17 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 guidance in USP–797 is followed in assigning a longer BUD (e.g. 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 (e.g. the period of time over which an injection or infusion should administered, and when the medicine should be discarded).

37. I am practising in a community pharmacy. Do I need to be licensed by the TGA in order to compound and supply sterile injectable medicines?

The exemptions provided for in therapeutic goods legislation which allow pharmacists to compound medicines would allow for a pharmacist practising in a community pharmacy to compound and supply sterile injectable medicines, without having a manufacturing licence from the TGA.

If there was a plan to supply or sell the sterile injectable medicine by wholesale, then a manufacturing licence from the TGA would be required.

38. Where can I find a list of TGA licensed facilities that compound sterile injectable medicines?

A list of manufacturers that hold a TGA licence to compound sterile injectable medicinal products can be found via TGA's eBS portal: https://www.ebs.tga.gov.au. Select 'Public TGA Information' then 'Australian Manufacturers' then 'filter on 'Manufacturer Product Code' = 'compounded'.

39. If I am compounding sterile injectable medicines, do I need additional PII cover?

The guidance reminds pharmacists that they 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.

40. I am currently compounding sterile injectable medicines and have identified some changes that I need to implement in practice to ensure compliance with the guidance. How long will I have to implement the changes?

Pharmacists will have 6 months from the time of publication of the revised guidance to comply with it.

Pharmacists are reminded that they are already expected to be complying with the full set of compounding guidelines in their compounding practice, which requires them to:

- comply with all relevant practice standards, guidelines and legislation
- have good clinical and pharmaceutical evidence to support the quality, stability (including an appropriate 'in use expiry' and/or BUD), safety, efficacy and rationality of any extemporaneous formulation
- compound a medicine only where an appropriate commercial product is unavailable or unsuitable, and
- use sound judgement based on current clinical and pharmaceutical knowledge and risk assessment, before deciding whether to prepare a formulation for which there is no precedent in a reputable reference, and have documented evidence for their decision to compound.

Abbreviations

ARTG	Australian Register of Therapeutic Goods
APF	Australian Pharmaceutical Formulary and Handbook
CPD	Continuing professional development
TGA	Therapeutic Goods Administration