Guidelines on compounding of medicines review - response template

The Pharmacy Board of Australia is inviting feedback on its draft revised *Guidelines for compounding of medicines* (the draft revised guidelines). Optional questions have been provided below and you may wish to address some or all of these in your response.

Published submissions will include the names (if provided) of the individuals and/or organisations making the submission unless confidentiality is requested.

Do you want your responses to be published after public consultation?

☒ Yes, I want my responses to be published after public consultation

☐ No, I do not want my responses to be published after public consultation

Submissions for website publication should be sent in Word format or equivalent.[1]

Name: [redacted]

Organisation: Pharmaceutical Society of Australia

Contact email: [redacted]

Please note this response template contains the same questions as the online survey. Please choose only ONE method of responding to avoid duplicating your submission.

[1] We aim to publish documents in accessible formats (such as word files) to meet international website accessibility guidelines. Therefore, while you are welcome to supply a PDF file of your feedback, we ask that you also provide a text or word file. More information about this is available at https://www.ahpra.gov.au/About-Ahpra/Accessibility.aspx

	Question	Your feedback (include guideline number/section)
1	The revised compounding guidelines include additional content on medicine supply pathways to consider before deciding if it is appropriate to compound a medicine (Guideline 1 When to compound medicines). **Is the new content on medicine supply pathways clear and helpful? Why or why not?**	The new content is clear and helpful. We note that patients may be unhappy about having to use a more expensive commercial product. The 'Fact sheet for members of the public' may be a useful tool for pharmacists to use when explaining why the patient cannot access a compounded medicine that is cheaper than a commercial product.
2	The compounding guidelines advise that a copy of the formula for their compounded medicine (listing all active ingredients and their strengths, and all inactive ingredients) must be provided to the patient when requested (Guideline 13 Supporting informed patient choice). Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. **Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?**	PSA/APF support providing either the formula or list of ingredients and believe information about the ingredients should be included on the label (*Guidance 10 packaging and labelling requirements* may need to be amended because it doesn't align with labelling requirements for compounded medicines mentioned in APF). Providing the 'formula' may not be the same as providing a list of all ingredients. The term 'formula' could be taken to mean quantities of all ingredients and method of preparation. The distinction may be important from a compounding pharmacist's perspective-: • The 'formula' may give the compounding pharmacy a market advantage with respect to quality and efficacy of the compounded preparation. • The list of all ingredients may give necessary information to patients with allergies or adverse reactions to particular ingredients.
3	The revised compounding guidelines include content that is specific to medicines compounded for animal patients. **Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?**	The new content is clear and helpful. Pharmacists need to understand the differences between animal compounding and human compounding (e.g. animal compounding does not need to be for a specific named patient).
4	**Is there any content that needs to be changed, added or deleted in the revised guidelines? If so, please provide your suggestions and reasons.**	See markup/comments inserted on pdf
5	Is the language of the revised guidelines clear and is the structure helpful? Why or why not?	Language is generally clear – see some specific comments on pdf. Structure:

	Question	Your feedback (include guideline number/section)
		• '*Guidance 3 Quality assurance*' could be expanded to include SOPs and documentation • '*Guidance 1.1 Considerations before compounding a medicine*' could be expanded to include risk assessment • The separation of contextual information from the guidance is helpful in making the Board's guidance clear
6	**Please provide any other feedback about the revised guidelines.**	See markup/comments inserted on pdf
7	The Board proposes to retire the *Professional practice profile* for pharmacists undertaking complex compounding, as a professional practice profile should be practitioner specific, describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Individuals should develop their own practice profile by selecting the relevant competencies from the competency standards and customising them for use in their own practice setting. **Do you agree with the Board's proposal to retire the currently published *Professional practice profile* for pharmacists undertaking complex compounding? Why or why not?**	PSA/APF agrees that is it better to refer pharmacists to current Competency Standards
8	The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation. **Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?**	PSA/APF thinks that a fact sheet should be published on PBA website. See markup/comments inserted on pdf for suggested amendments. Would be really useful for PBA to produce a fact sheet that pharmacists can provide to consumers at any time to explain compounded medicines.

Public consultation paper

30 May 2023

Public consultation on the review of Guidelines on compounding of medicines

Summary

The Pharmacy Board of Australia (the Board) develops policies, codes and guidelines to provide guidance to the profession. In 2015, the Board published its *Guidelines on compounding of medicines* (the compounding guidelines), which set out guidance to registered pharmacists in relation to the compounding (extemporaneous preparation) of medicines, not set out in legislation or a registration standard.

The guidelines provide guidance to pharmacists in relation to the compounding of medicines to ensure product quality, safety and efficacy and clarify specific issues that must be considered by pharmacists when compounding medicines. These guidelines should be read in conjunction with:

- the Board's Code of conduct and guidelines for pharmacists
- codes and guidelines published by the local pharmacy premises regulatory authority or equivalent about premises requirements when compounding medicines in that jurisdiction
- the *Compounding* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook*
- relevant practice standards and guidelines published by the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia
- the Agricultural and Veterinary Chemicals Code (AgVet Code) when compounding for animal patients
- occupational, health and safety standards, and
- Australian standards for clean rooms.

Under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), regulatory guidelines have a special status. They can be used as evidence of appropriate professional practice or conduct. To update or amend guidelines, wide ranging consultation is required.

The main changes proposed are for the Board to:

- revise the *Guidelines on compounding of medicines*, and
- retire the Professional practice profile for pharmacists undertaking complex compounding.

As part of the Board's review of its compounding guidelines, it will also revise its additional resources such as the background document and FAQ document. The Board has also developed a consumer fact sheet to increase consumer understanding of compounded medicines. These additional resources are not the subject of this consultation.

More information about the proposed changes is included in this consultation paper. The consultation is open until close of business on Monday 24 July 2023.

Providing feedback during public consultation

The Board is releasing this public consultation paper for feedback on its draft revised *Guidelines for compounding of medicines* (the draft revised guidelines). Specific questions have been provided, which you may wish to address in your response.

You are invited to give feedback on the draft revised guidelines at Attachment A.

You can provide feedback by close of business on **Monday 24 July 2023** by one of two ways:

1. submitting your answers to the questions via an online survey

   OR

2. using the response template and sending it as a Word document (not PDF) by email to PharmBAFeedback@ahpra.gov.au

Submissions for website publication should be sent in Word format or equivalent.[1]

Publication of submissions

Submissions are published at the discretion of the Board and Australian Health Practitioner Regulation Agency (Ahpra). Generally, submissions are published on our websites to encourage discussion and inform the community and stakeholders. Please advise us if you do not want your submission published.

We will not place on our websites, or make available to the public, submissions that contain offensive or defamatory comments or are outside the scope of the subject of the consultation. Before publication, we may remove personally identifying information from submissions, including contact details.

The Board and Ahpra can accept submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the Freedom of Information Act 1982 (Cth), which has provisions designed to protect personal information and information given in confidence. Please let us know if you do not want us to publish your submission or want us to treat all or part of it as confidential.

Published submissions will include the names of the individuals and/or the organisations that made the submission unless confidentiality is requested.

Next steps

After the public consultation closes, the Board will review and consider all feedback before making decisions about implementation and its supporting documents.

The Pharmacy Board of Australia acknowledges the Traditional Owners of Country throughout Australia and their continuing connection to lands, waters and communities. We pay our respect to Aboriginal and Torres Strait Islander cultures and Elders past and present.

[1] We aim to publish documents in accessible formats (such as word files) to meet international website accessibility guidelines. Therefore, while you are welcome to supply a PDF file of your feedback, we ask that you also provide a text or word file. More information about this is available at https://www.ahpra.gov.au/About-Ahpra/Accessibility.aspx

Contents

Background **4**

Overview **4**

What are guidelines? 5

Consultation on changes to the guidelines **5**

Guidelines on compounding of medicines 6

Medicine supply pathways 6

Ingredient information 7

Supplementary information about compounding **7**

Background on the regulation of compounding by pharmacists 7

FAQ for pharmacists on the compounding of medicines 7

Professional practice profile 7

Consumer fact sheet 8

Case studies **8**

Case study 1 – Risk assessment 8

Case study 2 – Combination medicine not entered on ARTG 9

Case study 3 – Medicine shortage 9

Case study 4 – Supply within a timeframe that meets the patient's needs 10

Case study 5 – Medicine becomes commercially available after compounding 10

Case study 6 – Confidential ingredients 11

Case study 9 – Competency and Training 12

Questions for consideration **12**

Options considered by the Board **13**

Option one - Status quo 13

Option two – Develop revised guidelines 13

Option three – Retire the guidelines 13

Preferred option 13

Relevant section of the National Law **13**

Estimated impacts of the revised guidelines **13**

Attachments **14**

Background

The role of the Pharmacy Board of Australia (the Board) is to work with the Australian Health Practitioner Regulation Agency (Ahpra) and other National Boards to achieve the objectives of the National Registration and Accreditation Scheme (the National Scheme), which has public safety at its heart.

The Board develops registration standards, codes and guidelines under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). These documents:

- set out the requirements for registration
- establish obligations for professional practice, and
- can be used as evidence in disciplinary proceedings of what constitutes appropriate professional conduct or practice for the profession.

The Board regularly reviews its standards, codes and guidelines to make sure they remain relevant, contemporary and effective.

The Board has developed guidelines to provide guidance to the profession not set out in the legislation or a registration standard. They provide interpretation for pharmacists and help to clarify the Board's views and expectations on a range of issues in the public's interest.

The *Guidelines on compounding of medicines* acknowledge the relevance in practice of:

- state, territory and Commonwealth legislation
- professional practice standards and guidelines
- where relevant, the codes, guidelines and/or requirements of other authorities, and
- the *Compounding* section in the current edition of the *Australian pharmaceutical formulary and handbook,* a primary reference which informs the education of students and pharmacists and the compounding of medicines in pharmacy practice.

Overview

The Pharmacy Board of Australia (the Board) is reviewing the *Guidelines on compounding of medicines* (the guidelines).

Compounding guidance was first developed in preparation for the National Scheme commencing in mid-2010 and was included in the *Guidelines for dispensing of medicines*. As a result of an incident in the United States when the compounding of a steroid injection resulted in fungal meningitis, which adversely affected more than 700 patients and resulted in the death of more than 60 people, the guidance was reviewed. Separate stand-alone compounding guidelines were published in April 2015.

In 2015, the Board published other relevant resources to support practitioners, which provided clarification about issues related to the compounding of medicines and information on the regulatory environment for compounding by pharmacists. The resources listed below will be reviewed and updated before the revised guidelines are published and ahead of their implementation:

- Background on the regulation of compounding by pharmacists
- FAQ for pharmacists on the compounding of medicines

Subsequent feedback from stakeholders on the Board's guidance on the expiry of compounded parenteral (injectable) medicines highlighted concerns that the guidance would inhibit or impact access to such medicines. As a result, the Board postponed the commencement of this section of the guidelines and conducted further consultation. Amended guidance for the compounding of sterile injectable medicines took effect on 1 February 2018.

The guidelines are now due for review and through this consultation the Board is seeking your feedback on its proposed revisions. Under the National Law, wide-ranging consultation is required before guidelines are updated or amended.

What are guidelines?

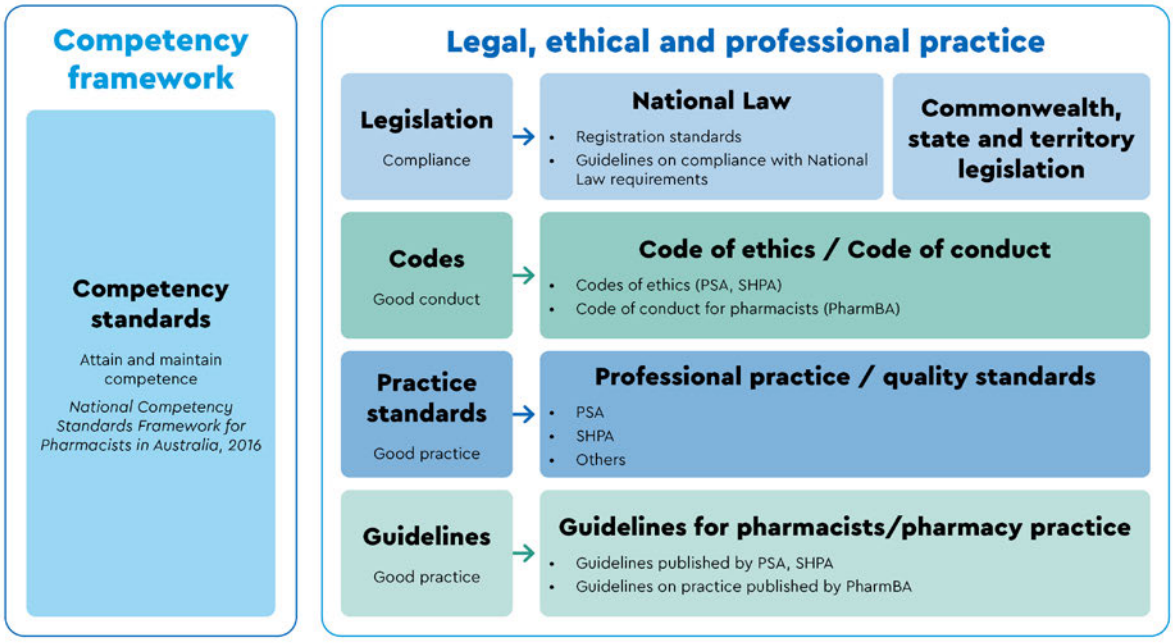
When we refer to guidelines in this paper, we mean guidelines developed under the National Law in the context of practitioner regulation. The National Law says that guidelines have two purposes. They:

- can be used to guide the profession, and
- are evidence of appropriate professional practice or conduct in a disciplinary proceeding against a practitioner.

The Board typically uses guidelines to explain its registration standards, the National Law and the way it regulates. Guidelines are generally high-level guiding documents, but not usually about specific areas of clinical practice.

Guidelines under the National Law are distinct from practice guidelines developed by professional associations or other entities that provide detailed advice on a specific area of clinical practice.

The following diagram illustrates the broad range of information that supports professional practice:



Note: In the above diagram:

- *PharmBA means the Pharmacy Board of Australia*
- *PSA means the Pharmaceutical Society of Australia*
- *SHPA means the Society of Hospital Pharmacists of Australia.*

Consultation on changes to the guidelines

The proposed changes to the guidelines are reflected in the revised guidelines at Attachment A. A table mapping the changes is provided at Attachment B – Summary of proposed changes to Guidelines on compounding of medicines.

For information, below are links to the current published guidelines and supporting documents available on the Board's website.

Link to the current Guidelines on compounding of medicines
Link to the current Professional practice profile for pharmacists undertaking complex compounding
Link to the current Background on the regulation of compounding by pharmacists
Link to the current FAQ for pharmacists on the compounding of medicines

Principles that informed the review / changes

When reviewing the guidelines, the Board considered the following:

- Objectives and guiding principles of the National Scheme
- The Regulatory principles of the National Scheme
- Policy Direction 2019-02
- Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025, and
- Ahpra's procedures for the development of registration standards, codes and guidelines.

As a result of the review guided by the above documents, the Board is proposing an outcome that:

- promotes professionalism and supports practitioners
- reduces unnecessary duplication of regulation
- can be complied with by individual practitioners
- is proportionate to the risks posed and not excessive
- does not produce guidance that duplicates existing legal obligations or professional practice standards, and
- was reached through an open, transparent and consultative process.

The changes proposed were informed by:

- input and feedback from key stakeholders
- feedback from members of the profession
- changes internationally and within Australia that relate to compounding by pharmacists
- input from National Boards, and
- feedback from the Board's committees.

Guidelines on compounding of medicines

The main changes proposed to the guidelines are:

- additional guidance on when it may be appropriate to compound a medicine
  - included a revised definition of a 'commercial medicine'
  - consideration of other pathways to access commercial medicines
- removal of information that duplicates essential references such as the *Australian Pharmaceutical Formulary and Handbook (APF)**
  - removal of detailed information in relation to setting expiry dates for sterile injectables
- highlighting when the guidance for animal patients is different to the guidance for human patients
- where possible, separating Board guidance from contextual information such as applicable legal requirements and the standards of practice as published by the profession
- reorganised content to reduce duplication and make the sequence of information more logical, and
- minor changes to refine and clarify wording and expression throughout the guidelines.

*Note: APF's revised compounding section with additional chapters and information on compounding sterile and hazardous medicines is planned for publication in January 2024.

Medicine supply pathways

Medicines can be accessed via other pathways set out in legislation that may provide a suitable alternative for the patient to a medicine entered on the Australian Register of Therapeutic Goods (ARTG) (refer to the Board's *Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists* document). A decision to compound a medicine should consider an available medicine which can be accessed through these pathways and whether it is an appropriate alternative for the patient.

Compounding may be an appropriate option if a medicine available through other supply pathway is assessed as not appropriate for the patient. This may be due to one or more factors, for example, the pathway does not provide access within the timeframe needed to commence the treatment, there is insufficient information available about the quality of the product etc.

Ingredient information

For most commercial medicines, the Consumer Medicine Information leaflet (often readily available online), will have a list of the excipients included in the medicine. This list can be found under 'Product description'. For medicines entered on the ARTG, a list of excipients can also be found on the Therapeutic Goods Administration (TGA) website, in the ARTG summary for the medicine. The ARTG summary lists the formulation of the medicine, with inactive ingredients in alphabetical order.

A patient using a compounded medicine should have access to a list of ingredients, as with a commercial medicine. Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. If a pharmacist wishes to have proprietary ingredient formulations such as a cream base or a flavour, this is regulated by the TGA.

Supplementary information about compounding

Background on the regulation of compounding by pharmacists

The Board currently publishes on its website as a separate information sheet, background information on the regulatory requirements that enable pharmacists to compound medicines in certain circumstances for human and animal patients. This is not part of the draft revised guidelines or the current consultation, as it relates to the requirements addressed in the legislation administered by other regulators such as the Therapeutic Goods Administration (TGA) and the Australian Pesticide and Veterinary Medicines Authority (APVMA). The information included in this published document has been reviewed and revised to complement the proposed changes to the guidelines to provide information on lawful pathways to access medicines, of which compounding is one. The revised document is attached to this consultation paper and will be on the Board's website alongside the published final version of the guidelines.

FAQ for pharmacists on the compounding of medicines

The Board developed frequently asked questions (FAQs) to provide pharmacists with additional information and clarification on a range of issues relating to the compounding of medicines. The FAQs are to be considered in conjunction with the Board's *Guidelines on compounding of medicines*, any documents referred to in the guidelines, and the Background on the regulation of compounding by pharmacists published by the Board. The FAQs are not part of the draft revised guidelines or the current consultation. The FAQs will be reviewed and updated once the guidelines are finalised to incorporate any additional information that may further clarify issues relevant to the compounding of medicines.

Professional practice profile

In 2015 the Board published a resource, *Professional practice profile for pharmacists undertaking complex compounding* (practice profile), to support the introduction of specific guidance on matters relating to complex compounding. To develop the practice profile, the competencies relevant to compounding from the *National Competency Standards Framework for Pharmacists in Australia, 2010* (the competency standards), were customised to articulate the competencies required to provide complex compounding services.

The purpose of the practice profile was to help pharmacists understand the performance expected when undertaking complex compounding and consequently to identify any necessary action to take before providing these services e.g. continuing professional development activities such as a training program on complex compounding, training in suitable premises and/or other suitable activities. The practice profile and professional practice standards on compounding could also be used by training program providers to develop programs for delivery to pharmacists seeking to extend their scope of practice to include complex compounding.

The practice profile includes the competencies and evidence examples to show the behaviour expected of a competent pharmacist whose sole professional function is to undertake complex compounding. It was designed as a tool for pharmacists to understand and achieve the performance expected when undertaking complex compounding. The practice profile enables pharmacists undertaking complex compounding to:

- identify the competencies relevant to their practice
- reflect on their continuing professional development needs
- develop a learning plan, and

- undertake activities to address their learning needs.

The competency standards outline that pharmacists must use the competency standards to create a personalised professional practice profile that describes their scope of practice and their desired performance level. Individuals should select the relevant competencies from the competency standards and customise them for use in their particular setting. A practice profile for complex compounding should be practitioner specific and describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Pharmacists would need to adapt the practice profile or develop their own to reflect their individual scope of practice.

The practice profile is no longer current as it is based on the competencies of the National Competency Standards Framework (2010). A review of the 2010 competency standards framework commenced in 2014 and a revised and updated framework was published in 2016. The current competency standards framework is currently due for review again.

The professional practice profile has not been reviewed and updated as the Board proposes to retire this document. The Board has not developed a practice profile for other scopes of practice and does not regulate scope of practice. Professional organisations may develop professional practice profiles or assist their members to develop a personalised practice profile.

Fact sheet for members of the public

The fact sheet for members of the public was developed by the Board to provide helpful context for members of the public to participate in the consultation. The fact sheet aims to explain why pharmacists compound some medicines and how compounded medicines are different to other medicines. The content of the fact sheet is not part of the draft revised guidelines.

The Board will explore during this consultation if the fact sheet should be published on the Board's website so that it can be accessed by pharmacists and members of the public in its published form or where appropriate, modified by pharmacists to suit its recipients.

Case studies

To assist in understanding the application in practice of the revised guidelines, the Board has developed the following case studies. The case studies are not intended to address all types of compounding scenarios, complex scenarios or all relevant potential considerations required when compounding a medicine. The case studies are designed to show how guidance can be applied and to illustrate specific guidelines only.

Case study 1 – Risk assessment

A pharmacist working at a pharmacy that regularly compounds medicines realises that an individual risk assessment is not carried out with each prescription and that the pharmacy often reuses the risk assessment for the same medicine when compounded for different patients.

The pharmacist has recently read the Board's compounding guidelines, which state that a risk assessment that includes the clinical justification for compounding should be completed and documented with each request for a compounded medicine (including repeats) and must consider any risks specific to the patient (*Guideline 1.1 – Considerations before compounding a medicine* and *Guideline 5.4 Risk assessment process for compounded medicines*).

The pharmacist discusses with fellow staff the requirement to complete an individual risk assessment including consideration of any patient-specific risks each time a medicine is compounded.

The revised guidelines highlight the importance of the risk assessment. The risk assessment must be used to provide the clinical justification for compounding the medicine and to assess the potential risks (to staff and the patient) associated with compounding a medicine.

If the compounded medicine is a repeat, it still requires a risk assessment to consider any factors that may have changed such as current medications or medical conditions, patient specific factors (e.g bodyweight, renal function) and other factors such as availability of a commercial medicine.

Case study 2 – Combination medicine not entered on ARTG

A pharmacist receives a prescription from a prescriber for a compounded medicine with two active ingredients.

The pharmacist knows that a combination product of the two ingredients is not listed on the Australian Register of Therapeutic Goods (ARTG), however they know that the medicines are available separately. The pharmacist checks the available strengths and determines that the two medicines are available in slightly different strengths to what has been prescribed.

The pharmacist consults the compounding guidelines (*Guideline 1 – When to compound medicines*) and decides not to compound the medicine as, although the combination medicine is not available on the ARTG, the individual medicines are available. In discussion with the prescriber, they also conclude that although the prescription states slightly different strengths, the medicines entered on the ARTG would meet the patient's needs as they would be unlikely to produce a different therapeutic outcome.

During discussions with the prescriber the pharmacist is able to establish that the sole justification for prescribing the compounded medicine was to enable the patient to take one medicine rather than two separate medicines and confirms there were no other reasons for prescribing a compounded medicine (e.g. allergy). The prescriber indicates they were advised that the patient had been taking this medicine and had prescribed it again for continuity. The pharmacist discusses the alternative suitable medicines that are entered on the ARTG, are available and may address the patient's needs with the patient and the prescriber. The alternative medicines entered on the ARTG are agreed by the prescriber to be suitable for the patient, and the medicine is not compounded.

The revised guidelines state that if an appropriate combination of commercial medicines is available and suitable for the patient, a pharmacist must not compound the medicine (including if the medicine can be compounded at a lower price than the available commercial medicine) or compound a slightly different medicine where it is unlikely to produce a different therapeutic outcome. Medicines that are entered on the ARTG have been evaluated for quality, safety and, where appropriate, efficacy and/or performance. This case study highlights that there are several important considerations to inform how to respond to a request for a compounded medicine.

Case study 3 – Medicine shortage

A pharmacist receives a prescription for Prednefrin Forte® (prednisolone and phenylephrine) eye drops. They are competent in the compounding of sterile eye drops and the pharmacy regularly compounds these types of medicines. The pharmacist knows the eye drops are currently in shortage, so they consider whether to compound and consult the compounding guidelines (*Guideline 1 – When to compound medicines*). This leads them to check the TGA website for options to access a medicine during a shortage and, subsequently, the Database of section 19A approvals to import and supply medicines to address medicine shortages. The database shows that while Prednefrin Forte® is in shortage, Pred Forte® (prednisolone acetate 10mg/mL) eye drops (UK) have been approved for supply.

The pharmacist also checks the list of Section 19A medicines subsidised by the Pharmaceutical Benefits Scheme and determines that Pred Forte® is PBS subsidised to manage the shortage of Prednefrin Forte®. However, it is not flagged as bioequivalent to Prednefrin Forte® in the Schedule of Pharmaceutical Benefits due to differences in active ingredients. The pharmacist contacts the prescriber and explains the shortage of Prednefrin Forte®, the alternative eye drops that can be accessed and are available now, and how the active ingredients are different (no phenylephrine). The prescriber agrees that the alternative eye drops will meet the therapeutic needs of the patient and will be a suitable alternative. The prescriber supplies a new prescription for the alternative eye drops.

The pharmacist explains the change to the patient when supplying the medicine.

The revised guidelines now include an amended definition of a 'commercial medicine' and further clarify that all lawful medicine supply pathways must be considered by the pharmacist and any suitable options discussed with the patient and the prescriber. Any alternative commercial product considered should be accessible in the time frame that meets the patient's needs. The *Background on the*

regulation of the supply and manufacture of medicines including medicines compounded by pharmacists document outlines a range of pathways to consider before deciding to compound.

Case study 4 – Supply within a timeframe that meets the patient's needs

A pharmacist receives a prescription for an oral suspension to be compounded. They check and neither the medicine nor any suitable therapeutic alternatives are entered on the ARTG.

The pharmacist consults the compounding guidelines (*Guideline 1 – When to compound medicines*) and considers pathways for supply of medicines not entered on the ARTG. They determine that the medicine could be accessed via the Special Access Scheme, or that it could be compounded.

After consulting with the patient, the pharmacist determines that the patient is required to commence the medicine within the next 48 hours. The pharmacists considers the pathways for supply and determines that the only appropriate option is to compound the medicine so the patient can commence the treatment within the required timeframe. The pharmacist explains to the patient that the medicine will be compounded and is not subject to the same processes as approved medicines and the patient consents to receiving a compounded medicine.

The pharmacist conducts a risk assessment, which includes the clinical justification for compounding.

As the prescription has repeats, the pharmacist explores if supply pathways other than compounding would enable the patient to access a suitable medicine on an ongoing basis.

The revised guidelines further clarify that all lawful medicine supply pathways must be considered by the pharmacist and any suitable options discussed with the patient and the prescriber to determine if compounding the medicine is the most appropriate option. If a commercial medicine cannot be accessed within the timeframe that the medicine is required for use by the patient, compounding the medicine can be considered.

Case study 5 – Medicine becomes commercially available after compounding

A pharmacist has been compounding a medicine that has not been entered on the ARTG for a patient at their pharmacy on a regular basis over the past few years. The patient brings in a repeat for the medicine, but the pharmacist knows that there are now products entered on the ARTG, which have recently become available.

The pharmacist checks the compounding guidelines (*Guideline 1 – When to compound medicines*) and realises that products that are available on the ARTG must be considered before compounding the medicine. They explain to the patient that a pharmacist can only compound a medicine when a commercial medicine is unavailable or unsuitable and that there are now products available which are assessed for quality and safety. Additionally, the pharmacist explains that being able to compound the medicine at a lower price than the commercially available product is not a reason to compound.

The pharmacist consults with the patient and prescriber and determines there is no reason that the medicine entered on the ARTG is unsuitable for the patient. They decide not to compound the medicine for this patient as there is now a product available and approved for supply in Australia, which will address the patient's needs.

The revised guidelines further clarify that a medicine should not be compounded if a commercial medicine becomes available, is suitable and can be accessed within the timeframe that the medicine is required for use by the patient.

Other circumstances may result in compounding still being the appropriate option which highlights the requirements to clearly understand the patient's needs and to consult with the patient and prescriber as required.

A non-TGA licensed facility such as a community pharmacy may be able to compound a medicine at a lower price than the commercially available product as licensed manufacturers are required to comply with manufacturing and quality assurance processes that can increase the cost of the medicine. Providing compounded medicines to patients whose needs could be met by one or more medicines

entered on the ARTG can undermine the drug development and approval process by which the public have access to a wide range of quality medicines.

Case study 6 – Confidential ingredients

A pharmacist compounds a prescribed cream for a patient and only labels the cream with the two active ingredients specified on the prescription. The label states that it is the pharmacist's 'own cream'. The patient requests a copy of the list of all ingredients included in the cream, however the pharmacist refuses, as it is their own cream they have developed and they do not want other pharmacists to know what the ingredients are.

The patient experiences a severe skin reaction and is admitted to hospital. While in hospital the patient is asked if they have used any new products and the patient provides the jar of cream they recently had compounded. The hospital contacts the pharmacist to find out all ingredients contained in the cream as only the two active ingredients are listed. It is subsequently established that the patient has an allergy to an excipient used in the cream.

The pharmacist reviews the revised compounding guidelines (*Guideline 5.5 – Consistency of supply* and *Guideline 13 – Supporting informed patient choice*) and realises that there should not be 'secret' ingredients. The pharmacist now includes a list of all ingredients on the label or, if there is insufficient space, they provide the patient with a copy of the list of ingredients included in the compounded medicine.

The revised guidelines provide further clarification that pharmacists should not have 'proprietary' or 'secret' ingredients for compounded products. Changing the formula from that of previous supplies could result in changes to the clinical effect of the product and have consequences for the patient. Providing the patient with a copy of the ingredients will also assist other treating practitioners in cases where the patient may experience an adverse reaction to an excipient in the compounded medicine.

To ensure patient safety, a list of the active ingredients (with strengths specified) and inactive ingredients in their compounded medicine must be provided to the patient.

Case study 8 – Unsuitable commercially available medicine

A pharmacist receives a prescription for a compounded oral suspension for a child for which there is a commercially available product available in the same form.

The pharmacist consults with the child's parents who explain that their child has a diagnosis of Austism Spectrum Disorder with marked sensory traits that make giving medicines very difficult. Specifically, the child will refuse any food or medicine coloured red, becoming extremely distressed. The parents produce a letter from the prescribing doctor that confirms this and requests that the medication be compounded as the commercial product is red in colour.

The pharmacist consults the available product information for the commercially available product and confirms that it is red in colour.

The pharmacist consults the compounding guidelines (*Guideline 1 – When to compound medicines*) and considers all the necessary factors before deciding to compound a medicine. The pharmacist determines that there are no other suitable commercial medicines that would be likely to produce the same therapeutic outcome.

The pharmacist completes a risk assessment that includes a clinical justification for compounding and decides that compounding the medicine as prescribed is an appropriate course of action. The pharmacist obtains informed consent from the child's parents and proceeds to compound the medicine.

The revised guidelines describe factors that should be considered by a pharmacist before compounding a medicine. One of the circumstances in which a medicine may be considered suitable for compounding is if a commercial medicine is unsuitable for the patient. This case study gives an example of where compounding a medicine is an appropriate course of action.

Case study 9 – Competency and Training

A pharmacist who has recently started work at a compounding pharmacy receives a prescription for a medicine to be compounded for animal use. The pharmacist has only recently begun complex compounding and has undertaken no prior CPD in the compounding of medicines for the treatment of animals. The employer is present and directs the pharmacist to proceed with compounding the medicine.

The pharmacist has familiarised themselves with the revised compounding guidelines, which state that if a pharmacist has not achieved competence to undertake a specific compounding task/activity, this task/activity should not be carried out by the pharmacist until competence is achieved (*Guideline 2 – Competence to undertake compounding*). The pharmacist raises this with their employer and requests that another pharmacist who has achieved competence in this area is allocated this task until they have undertaken suitable CPD to address this gap in competency. The employer agrees and proceeds to compound the medicine themselves, as they are competent in compounding medicines for the treatment of animals.

The employer then reviews the revised compounding guidelines and the Board's *Guidelines for proprietor pharmacists* and in taking steps to ensure that staff members are suitably trained, considers options for a training program for the new pharmacist in compounding medicines for animal use. The employer works with the pharmacist to facilitate undertaking suitable CPD to enable them to achieve competence in compounding medicines for the treatment of animals.

The revised compounding guidelines align with, and should be read alongside, the Board's Code of Conduct and the *National Competency Standards Framework for Pharmacists, 2016 (the Framework)* which address competency and CPD more broadly. This case study provides a specific example of where a pharmacist may not be competent to compound a prescribed medicine, and what steps can be taken both to ensure compounding is undertaken to ensure public safely, and to address training needs to achieve competence for the future.

Questions for consideration

The Board is inviting general comments on the revised guidelines and related documents, as well as feedback on the following questions:

The revised compounding guidelines include additional content on medicine supply pathways to consider before deciding if it is appropriate to compound a medicine (Guideline 1 When to compound medicines) **1. Is the new content on medicine supply pathways clear and helpful? Why or why not?**
The compounding guidelines advise that a copy of the formula for their compounded medicine (listing all active ingredients and their strengths, and all inactive ingredients) must be provided to the patient when requested (Guideline 13 Supporting informed patient choice). Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. **2. Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?**
The revised compounding guidelines include content that is specific to medicines compounded for animal patients. **3. Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?**
4. Is there any content that needs to be changed, added or deleted in the revised guidelines? If so, please provide the details and suggestions and reasons why.
5. Is the language of the revised guidelines clear and is the structure helpful? Why or why not?

6. Please provide any other feedback about the revised guidelines.
The Board proposes to retire the *Professional practice profile for pharmacists undertaking complex compounding*, as a professional practice profile should be practitioner specific, describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Individuals should develop their own practice profile by selecting the relevant competencies from the competency standards and customising them for use in their own practice setting. **7. Do you agree with the Board's proposal to retire the currently published *Professional practice profile for pharmacists undertaking complex compounding?* Why or why not?**
The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation. **8. Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?**

Options considered by the Board

Option one - Status quo

The guidelines have not been reviewed for some time and the current version was published in 2015. There have been several developments since then and, while available information suggests the guidelines are working reasonably well, there are several opportunities to improve the guidance. The improvements include revising content to remove duplication with primary references and providing further guidance on when it may be appropriate to compound a medicine.

Maintaining the status quo of the guidelines would miss these opportunities for improvement and result in the guidelines becoming progressively less contemporary and relevant.

Option two – Develop revised guidelines

Reviewing and revising the guidelines will ensure that they continue to be relevant, contemporary and aligned with local and international practice standards. It will capture the opportunities that would be missed in option one. It will provide an opportunity to consult stakeholders and in particular practitioners and the public to advise how the guidelines can be more relevant and helpful, in the public's interest.

Contemporary guidelines will provide consumer, regulatory, employer and professional bodies with clear guidance about the National Boards' expectations of the professional conduct of the practitioners they regulate in the public's interest.

Option three – Retire the guidelines

The compounding of medicines can pose a significant risk to the public. Retiring the guidelines would result in a gap between the Therapeutic Goods Legislation, practice standards and other published guidance. Additional guidance for pharmacists to compound medicines safely is still required.

Preferred option

The Board prefers option two and has drafted revised guidelines for consultation.

Relevant section of the National Law

The relevant sections of the National Law are Sections 39, 40 and 41.

Estimated impacts of the revised guidelines

The impacts on practitioners, businesses and other stakeholders arising from the changes proposed in the revised guidelines are expected to be small. The changes proposed are minimal and focus on providing explanation, clarification and removal of duplication of information with primary references.

Attachments

Attachment A: Revised draft Guidelines on compounding of medicines

Attachment B: Summary of proposed changes to Guidelines on compounding of medicines

Attachment C: Fact sheet for members of the public

Attachment D: Revised *Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists* document (not yet published, subject to further revision)

Attachment E: Statement of assessment - National Board's statement of assessment against Ahpra's Procedures for the development of registration standards, codes and guidelines and principles for best practice regulation

Attachment F: Patient and consumer health and safety impact statement

Attachment A

Draft revised Guidelines on compounding of medicines

May 2023

Contents

Who needs to use these guidelines? 2
How to read this document 2
Introduction 2
Relevant legislation, quality standards and practice standards 3
What happens if I do not comply with these guidelines? 5
Guidelines 6
1 When to compound medicines 6
Medicines for human use 6
Veterinary medicines 7
1.1 Considerations before compounding a medicine 8
1.2 Obligations when a prescribed or requested medicine cannot be compounded 10
2 Competence to undertake compounding 11
Veterinary medicines 11
3 Quality assurance 13
3.1 Sterile medicines 13
3.2 Self-assessment and audit 13
4 Facilities, equipment, working environments, materials and support staff 14
Starting materials 14
4.1 Risk assessment process for facilities and equipment 15
4.2 Starting materials 15
4.3 Supervision of support staff 15
5 Formulation considerations 17
5.1 Formulations for which precedents do not exist 17
5.2 Quantity to be supplied 18
5.3 Modification of commercial medicines 18
5.4 Risk assessment process for compounded medicines 18
5.5 Consistency of supply 19
6 Assigning expiry dates to compounded medicines 20
Expiry dates of compounded sterile injectable medicines 20
7 Batch preparation 21
8 Managing risks that may lead to injury 22
9 Documentation 23
10 Packaging and labelling requirements 24
11 Counselling and provision of information on compounded medicines 25
12 Reporting of adverse events 26
13 Supporting informed patient choice 27
14 Advertising 28
15 Reference texts and other sources of information relevant to compounding 29
Definitions 30
Board references 31
Review 32

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They detail the Board's guidance to registered pharmacists in relation to the compounding (extemporaneous preparation) of medicines, not set out in legislation or a registration standard. The Board may publish additional information about the compounding of medicines.

Who needs to use these guidelines?

These guidelines were developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to pharmacists holding the following types of registration:

a) general
b) provisional, or
c) limited.

These guidelines do not apply to students. However, students should become familiar with them before undertaking supervised practice placements.

How to read this document

The Board guidelines have been separated into context and guidance. The information contained in the context provides important information such as references to legislation, standards and essential references such as the Australian Pharmaceutical Formulary and Handbook. The Board guidance must not be read in isolation of the contextual information.

Guideline title

(*Context:*
- *factual information, references to legislation, practice standards and essential references such as the APF*
- *information that is not requirements or standards determined by the Board*)

Guidance

(*Board guidance:*
- *what the Board is advising pharmacists)*

Introduction

These guidelines are intended to support good practice by pharmacists when compounding medicines for human and animal patients. Pharmacists who compound medicines or oversee the compounding of medicines must ensure that at, all times, compounding practices are:

- compliant with relevant legislation
- compliant with relevant professional pharmacy practice standards and guidelines
- compliant with relevant guides and standards for good manufacturing practice
- informed by reputable sources of published information such as reference texts and peer reviewed journals
- supported by accepted evidence of safety, quality and efficacy
- delivered with the support of staff who are appropriately trained, educated and/or experienced in the type of compounding being undertaken
- carried out in facilities that are adequately designed, equipped, maintained and resourced
- aligned with the conduct expected of pharmacists as set out in the Board's code of conduct for pharmacists and the codes of ethics for pharmacists
- compliant with all relevant Board guidelines for pharmacists, and

- covered by professional indemnity insurance arrangements that comply with the Board's Registration standard: Professional indemnity insurance arrangements.

In addition to providing guidance for pharmacists compounding a medicine, these guidelines also set out the obligations of pharmacists responsible for the operation of the pharmacy premises where the compounding occurs. Depending on the practice setting, the person responsible for the operation of the premises may include (but not limited to) the:

- director of a hospital pharmacy department or their delegate
- pharmacist in charge,
- proprietors of a community pharmacy
- pharmacy manager and/or
- manufacturing licence holder.

The responsible person may also be defined in state and territory legislation.

These guidelines are not a substitute for – and must be read in combination with – the above sources of information. These guidelines do not restate or summarise essential reference material such as the *Australian Pharmaceutical Formulary and Handbook* and practice standards on compounding published by the professional associations.

If there is any conflict between these guidelines and the law, the law takes precedence.

Failure to adhere to these guidelines and the above standards and requirements may result in poor practice, which may be referred to the Board for investigation and possible action under the National Law.

The term 'patient' in these guidelines means a person receiving healthcare from a registered health practitioner or an animal receiving healthcare from a veterinarian. It includes clients and consumers. Depending on the context of practice and recognising the importance of patient-centred care, the term 'patient' can also extend to families and carers (including kinship carers), and to groups and/or communities as users of health services.

See *Definitions* at the end of this document for more terminology explanations.

Relevant legislation, quality standards and practice standards

Safe and quality compounding practices require compliance with legislation, quality and practice standards and related guidelines.

Legislation

Commonwealth, state and/or territory legislation sets out the obligations of pharmacists in relation to authority to compound medicines and the labelling, maintenance of records, storage, dispensing, supply and advertising of compounded medicines.

Compounded medicines for human use are not exempt from meeting the quality standards set out in the *Therapeutic Goods Act 1989* (Cth). The required specifications for compounded medicines include relevant standards of the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia, including relevant standards on microbiological quality of non-sterile pharmaceutical preparations.

The Board's information sheet *Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists* contains information on the requirements of other authorities under their specific legislation, which relate to compounding.

Quality standards

Adhering to principles and procedures in quality standards/guides is crucial for safe compounding practice. One or more of the following standards may be relevant depending on a pharmacist's compounding practice:

- the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010)
- the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009)
- the USP–NF ⟨795⟩ Pharmaceutical compounding—Nonsterile Preparations
- the USP–NF ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations.

The Therapeutic Goods Administration (TGA) have published guidance for TGA licensed manufacturers of extemporaneously compounded medicines, the *Compounded medicines and good manufacturing practice (GMP) - Guide to the interpretation of the PIC/S guide to GMP for compounded medicinal products*. Where possible this document should inform the compounding practices of pharmacists who are exempt from the requirement to hold a TGA licence to manufacture under Schedule 8 of the Therapeutic Goods Regulations 1990 (the Regulations).

The current version of USP-NF <800> may provide additional guidance on how pharmacists can meet their professional obligations when handling hazardous medicines.

Practice standards and guidelines

Pharmacists are expected to be aware of and comply with the practice standards and guidelines on compounding as listed below, including any other standards or guidelines referred to in those documents.

These guidelines must be read in conjunction with current (or equivalent) versions of:

- the Board's Code of Conduct and guidelines for pharmacists (see *Guidelines* at the end of this document)
- codes and guidelines published by the local pharmacy premises regulatory authority (or equivalents) about premises requirements when compounding medicines in that jurisdiction
- the Australian Pharmaceutical Formulary and Handbook
- the following practice standards and guidelines:
    - the Pharmaceutical Society of Australia (PSA) *Professional Practice Standards (v5) – Standard 5: Compounding*
    - The Society of Hospital Pharmacists of Australia (SHPA) *SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments*
    - The Society of Hospital Pharmacists of Australia *SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments*
    - The Society of Hospital Pharmacists of Australia *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments*
    - The Society of Hospital Pharmacists of Australia *SHPA Standard of practice in oncology and haematology for pharmacy services*
- the Agricultural and Veterinary Chemicals Code (AgVet Code) when compounding for animal patients
- occupational, health and safety standards, and
- Australian standards for clean rooms.

The pharmacy practice standards and guidelines listed above can be accessed on the websites of the relevant professional bodies:

- Pharmaceutical Society of Australia (www.psa.org.au)
- The Society of Hospital Pharmacists of Australia (www.shpa.org.au)

(Note:

1. *Information about the circumstances under which pharmacists may compound and supply extemporaneously prepared medicines in and from different types of premises can be accessed on the TGA website at www.tga.gov.au. (Except in Western Australia where state-specific requirements are on the WA Health website at ww2.health.wa.gov.au).*
2. *Pharmacy ownership, registration/licensing, regulation of premises, inspections and related matters do not fall under the National Law. Each jurisdiction may have legislation and guidelines relating to pharmacy premises, including requirements for compounding within premises.*

3. *Any additional guidelines and/or standards that are adopted by the pharmacy profession after these guidelines are published should be considered when compounding medicines.*
4. *Any relevant quality standards that are updated should be considered prior to their implementation date if available.)*

What happens if I do not comply with these guidelines?

Pharmacists must comply with all legislation relevant to the practice of pharmacy in their jurisdiction. Failure to practise in accordance with legal requirements may lead to action by authorities. Under the National Law, such matters may be referred to the Board for appropriate action or to a relevant regulatory body in a co-regulatory jurisdiction (see *Definitions*).

Non-compliance with these guidelines and the practice standards and guidelines relevant to compounding may also result in a notification to the Board or jurisdictional regulatory body. Such notifications may be made by an individual or as a result of other processes such as audits carried out by state/territory pharmacy premises regulators (or equivalents).

Under section 41 of the National Law and other jurisdictional laws, these guidelines can be used in disciplinary proceedings as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications against pharmacists, the Board considers whether these guidelines have been breached. The Board will also consider legislation, practice standards and guidelines relevant to pharmacy practice.

Further information for pharmacists on the possible outcomes of notifications is available on the of the Australian Health Practitioner Regulation Agency (Ahpra) website.

Guidelines

These guidelines apply to compounding medicines for humans and animals. When the guidance for animals is different to that for humans, it is specified. The guidance applies to both simple and complex compounding, unless otherwise stated (see *Definitions* at the end of this document).

Pharmacists may be required to manipulate a commercial medicine to make it 'ready to administer'. If this is in accordance with the manufacturer's instructions, for the purposes of these guidelines this is not considered compounding. Examples of this may include reconstituting oral antibiotic mixtures and aseptic transfer in accordance with the manufacturer's instructions.

Where a manufacturer's instructions are not followed, for example a different diluent is used or a flavouring is added to an oral mixture, this *is* considered compounding and these guidelines apply.

1 When to compound medicines

Various medicine supply pathways can be used to meet the needs of the public.

The Australian Register of Therapeutic Goods (ARTG) is the public database of therapeutic goods for human use that can be legally supplied in Australia. Medicines listed on the ARTG are most commonly accessed by pharmacists from pharmaceutical wholesalers.

Legislation also provides access to medicines via additional pathways that allow some medicines which are not listed on the ARTG to be imported into and accessed and supplied in Australia.

Pharmacists routinely use these alternative pathways to access medicines when it is appropriate for the patient. Compounding medicines may be appropriate and necessary when other pathways of accessing medicines are not suitable for the patient.

Medicines for human use

Medicines on the Australian Register of Therapeutic Goods (ARTG) have been evaluated for quality, safety and where appropriate, efficacy and/or performance and are the medicines most commonly prescribed and supplied in Australia. This drug approval process provides the public with assurances that their medicines meet quality, safety and efficacy standards.

Providing compounded medicines to patients whose needs could be met by one or more medicines on the ARTG can undermine the drug development and approval process by which the public have access to a wide range of quality medicines. Unnecessary compounding of medicines carries risks, for example:

- to the patient using a compounded medicine which has not undergone equivalent testing to medicines listed on the ARTG, and
- in the case of certain medicines (e.g. hazardous medicines) also carries risks to the pharmacist and other staff involved in the compounding.

Section 19A of the Therapeutic Goods Act 1989 allows medicines not currently included in the ARTG to be imported into Australia and supplied:

- in place of a registered medicine that is unavailable or in short supply, or
- if relevant registered medicines do not exist but an application for a new medicine is being evaluated by the TGA.

The TGA also administers other pathways that allow supply of medicines that are not included in the ARTG which include:

- the Special Access Scheme (SAS)
- the Authorised Prescriber (AP) Scheme
- avenues that provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial.

Some medicines may need to be compounded by pharmacists to meet the needs of the public, however the compounding can only take place when the circumstances enable a pharmacist to meet the provisions in relevant legislation, for example:

- in premises licensed by TGA and the medicine is entered on the ARTG
- in a community pharmacy, when the pharmacist has a prescription or order, and the patient has requested supply of the medicine before it is compounded
- in a hospital, when the pharmacist has received a prescription or order for the medicine before it is compounded, or 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 (as set out in the Therapeutic Goods Regulations 1990)
- a request for a compounded non-prescription medicine such as unscheduled, Schedule 2 or Schedule 3 medicines (as permitted by legislation) has been received from a patient before the medicine is compounded.

Further details are set out in the relevant provisions in the therapeutic goods legislation.

Veterinary medicines

As outlined in the *Agricultural and Veterinary Chemicals Code* (AgVet Code), compounded medicines are not defined as veterinary chemical products and are therefore exempt from registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Commercial medicines for animal use would be included in the APVMA PubCRIS database. Veterinary medicines containing scheduled or unscheduled medicines for animal patients can be compounded by a pharmacist if instructions have been received from a veterinary practitioner.

For further information about medicine supply pathways, refer to:

- *www.tga.gov.au*
- *www.apvma.gov.au*
- *Pharmacy Board of Australia Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists published at www.pharmacyboard.gov.au/Codes-Guidelines.aspx).*

Guidance

1.1 Considerations before compounding a medicine

For the purposes of these guidelines a 'commercial medicine' is a medicine that can be accessed in Australia through any pathway for the lawful supply of medicines. For human patients, this includes medicines on the ARTG and medicines accessed via pathways such as s19A, Special Access Scheme and others. A medicine compounded by a pharmacist under relevant exemptions to therapeutic goods legislation is **not** considered a commercial medicine for the purposes of these guidelines.

(Note: See *Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists* for information on the lawful supply of medicines in Australia including medicines exempt from entry on the ARTG.)

Consultation with the patient (or their agent) and their prescriber must occur when other supply pathways are more appropriate than compounding.

A decision by a pharmacist to compound a medicine is a professional decision for which the pharmacist is ultimately responsible and accountable. A risk assessment including a clinical justification for compounding must be completed for each request for a compounded medicine.

The following factors should be considered by a pharmacist before compounding a medicine:

1.1.1 The availability of a commercial medicine

Medicines should only be compounded in circumstances when:

a. an appropriate commercial medicine does not exist, is unavailable or cannot be accessed within the timeframe that the medicine is required for use by the patient, or
b. a commercial medicine is unsuitable (for example, if a patient has a known allergy to an excipient in the medicine or the dose forms available are unsuitable)
c. required for the purpose of research sanctioned by a recognised human research ethics committee

A medicine (whether prescribed by an authorised prescriber or not) should not be compounded if:

a. a commercial medicine is a suitable treatment option for the patient, or
b. the compounded medicine would be a close formulation to that of an available and suitable commercial medicine, or combination of commercial medicines, and is unlikely to produce a different therapeutic outcome, or
c. a commercial medicine becomes available, is suitable and can be accessed within the timeframe that the medicine is required for use by the patient.

If a suitable commercial medicine (or combination of commercial medicines), is available, a pharmacist must not:

a. offer to compound the medicine, including if the medicine can be compounded at a lower price than the available commercial medicine, or
b. compound a slightly different medicine that is unlikely to produce a different therapeutic outcome.

Note for animal patients:

Registered veterinary chemical products for use in Australia are assessed for quality, efficacy and safety. If a suitable registered veterinary chemical product (or combination of registered veterinary chemical products) is available, a pharmacist must not:

a. offer to compound the medicine, including if the medicine can be compounded at a lower price than the available veterinary chemical product, or
b. compound a slightly different medicine that is unlikely to produce a different therapeutic outcome to an available veterinary chemical product.

1.1.2 Competence to compound medicines

Medicines should only be compounded by pharmacists and other staff involved in the compounding of medicines who have completed education and training in the types of compounding they undertake, and they have demonstrated competence in the relevant compounding techniques.

1.1.3 The suitability of the compounding environment

Medicines should only be compounded if the compounding will take place in appropriate facilities and working environments and using appropriate equipment.

1.1.4 Evidence to support compounding is available

Medicines should only be compounded if there is accepted evidence of safety, quality and efficacy in reputable references, international pharmacopoeial standards, or peer reviewed journals. Decisions to compound medicines must not be based on testimonials and impressions.

1.1.5 Patient safety

Medicines must only be compounded if the pharmacist is satisfied that the dispensing and supply of a compounded medicine (including off-label use of medicines which are to be compounded into a medicine) is consistent with the safety of the patient (refer to Guideline 2 *Dispensing precaution – safety of prescriptions* of the Board's *Guidelines for dispensing of medicines*).

1.1.6 Patient consents to receiving a compounded medicine

The patient (or their agent) must be made aware that the medicine will be compounded and is not subject to the same processes as approved medicines and must consent to receiving a compounded medicine. This may not be possible in an emergency.

(Note: The Code of Conduct provides additional information about informed consent.)

1.2 Obligations when a prescribed or requested medicine cannot be compounded

If, after considering the factors set out in 1.1 and/or other relevant matters, the pharmacist decides not to compound the prescribed or requested medicine, the pharmacist should notify the patient and the prescriber that the medicine cannot be compounded and offer to discuss other suitable options that may address the patient's medication needs.

Also refer to the Board's *Code of Conduct for pharmacists*[1], which outlines that providing good care includes:

a. recognising the limits to a practitioner's own skills and competence and referring a patient to another practitioner when this is in the best interests of the patient
b. considering the balance of potential benefit and harm in all clinical management decisions
c. providing treatment options based on the best available information and not influenced by financial gain or incentives
d. consulting and taking advice from colleagues when appropriate
e. practising within an evidence-based and patient-centred framework, and
f. facilitating the quality use of therapeutic products based on the best available evidence and the patient's needs.

2 Competence to undertake compounding

Pharmacists entering the profession have had the appropriate education and training to compound medicines and are therefore deemed competent to undertake 'simple compounding'.

After entering the profession, some pharmacists may extend their scope of practice to compound medicines of a more complex nature (complex compounding – refer to *Definitions*), which requires and/or involves specific competencies, equipment, processes and facilities to manage the higher risks associated with the preparation and dispensing of these medicines.

The specific competencies relevant to complex compounding are outlined in the *National Competency Standards Framework for Pharmacists, 2016 (the Framework)* under *Creating an individualised professional practice profile*, which states:

"Pharmacists must use the competency standards to create a personalised professional practice profile that describes their scope of practice and their desired performance level …

… However, it is important to note that both individuals and organisations should select the relevant competencies from the Framework and customise them for use in their particular setting".

The Framework outlines the steps to develop a personalised practice profile for their scope of practice.

The Board's Code of Conduct describes the professional behaviour and conduct expected of pharmacists in relation to competence and continuing professional development (CPD). The Code states that good practice includes that you ensure that, when moving into a new area of practice, you have sufficient training and/or qualifications to achieve competency in that new area. For more information refer to Principle 7 and sections 1.2, 7.3 and 7.4 of the Code of Conduct.

When pharmacists extend their scope of practice to include complex compounding they are obliged to meet the requirements of the Board's CPD registration standard by planning and satisfactorily completing the CPD activities that address the competencies relevant to complex compounding and maintaining evidence of the activities completed.

Ongoing competency is maintained by ongoing practice and completion of CPD.

Veterinary medicines

Pharmacists who intend to compound simple and complex veterinary medicines are expected to have completed CPD (education and training) in the compounding of medicines for the treatment of animals. For more information on veterinary compounding, refer to the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook.*

Guidance

Demonstrating ongoing competence to undertake complex compounding, while ensuring public safety, the pharmacist's own safety and that of the staff working under their supervision, involves:

a. conducting a self-assessment to identify the competencies relevant to the areas of complex compounding being carried out,
b. identifying CPD needs relevant to these identified competencies and documenting these in the form of a CPD plan,
c. undertaking CPD activities (including a training program) that address identified continuing professional development needs, and
d. gaining experience under supervision until competent, in premises that are adequately designed, equipped, maintained and approved by relevant authorities, for example, a compounding pharmacy or a hospital pharmacy department.

Compounding of sterile or hazardous medicines involves significant risks and requires specific competencies. Pharmacists are encouraged to engage an expert or mentor to assist.

Pharmacists should seek information from continuing education providers on programs that address the specific competencies relevant to complex compounding.

The competence of pharmacists and other staff who prepare compounded medicines may be assessed and demonstrated by regular workplace validation, for example validation of aseptic or non-aseptic techniques (also refer to 3.2 *Supervision of support staff* and the practice standards listed in these guidelines).

If a pharmacist has not achieved competence to undertake a specific compounding task/activity, for example if the required training is currently unavailable, this task/activity should not be carried out by the pharmacist until competence is achieved.

3 Quality assurance

Quality assurance procedures and processes, including continuous quality improvement, are critical to ensure reliable, reproducible and consistently high-quality compounded medicines.

Pharmacists involved in compounding and persons responsible for the operation of premises including proprietors, are legally and professionally obligated to ensure that standard operating procedures (SOPs) are developed, implemented and routinely followed by all relevant staff for all compounding activities.

An authorised state, territory or Commonwealth entity may conduct an independent audit of a pharmacist's compliance with legislation, guidelines and practice standards. If such an audit identifies deficiencies or compliance breaches, these must be remedied by the pharmacist as directed by the authorised entity.

For more information about quality assurance including self-assessment and audit, pharmacists are referred to the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Guidance

3.1 Sterile medicines

When compounding sterile medicines, pharmacists must adhere to the principles and procedures outlined in one of the following guides/standard, whichever is the most appropriate and relevant to their compounding practice:

- 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.

In choosing the most appropriate and relevant guide or standard listed above, consideration must be given to all relevant factors including the practice setting, the types of medicines compounded, the risks identified during the risk assessment process for compounded products outlined in these guidelines and the risks to the patient and other individuals handling or exposed to the compounded medicines.

3.2 Self-assessment and audit

For all compounding (simple and complex), pharmacists must conduct a self-assessment/audit of their compounding practice against the relevant practice standards, guidelines and legislation.

Third party expertise may be required if compounding complex and high-risk medicines, for example:

a. to assist with auditing of compliance with regulatory requirements and any relevant standards, and
b. by submitting samples to an appropriately accredited analytical laboratory for testing according to documented testing protocols.

4 Facilities, equipment, working environments, materials and support staff

Pharmacists and persons responsible for the operation of premises, including proprietors, are legally and professionally obligated to ensure that all compounding takes place in premises that are adequately designed, equipped, maintained, resourced and staffed.

As required under relevant state and territory legislation, premises must be accredited and/or approved and/or registered by the relevant jurisdictional authority and operate in accordance with any legislation or guidelines published by those authorities.

The compounding practice standards and guidelines listed in these guidelines set out the facility, working environment and equipment specifications that must be met for the type of compounding carried out. The *Compounding* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook* also provides additional information.

In relation to complex compounding, pharmacists are legally and professionally obligated to refer to and comply with any occupational health and safety standards, state/territory legislation and the practice standards and guidelines listed in this document regarding specific facilities, working environments, equipment and safety precautions for:

a. the preparation of sterile and/or hazardous medicines to ensure medicines of an acceptable standard are produced, and
b. the handling of hormones, cytotoxics and other hazardous material to ensure the protection of pharmacy staff, patients and the public.

Additional information on facilities and equipment in relation to complex compounding (including sterile and hazardous medicines), is published in the *Compounding* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook.*

The Board's *Guidelines for proprietor pharmacists* sets out the responsibilities of proprietor pharmacists in relation to:

a. ensuring compliance with any state or territory legislation regarding facilities and equipment required for the types of compounding undertaken at the pharmacy, and
b. ensuring that the pharmacy is suitably resourced, and that staff members are suitably trained and appropriately supervised.

Starting materials

The *Australian Pharmaceutical Formulary and Handbook*, states that:

- All starting materials should be produced by manufacturers with suitably approved quality assurance and quality control procedures, including appropriate licensing and/or certification.
- Australian manufacturers should hold a Licence to Manufacture Therapeutic Goods issued by the TGA to manufacture the relevant ingredients.
- Overseas manufacturers should hold a certificate of GMP compliance or equivalent accreditation from a regulatory or accrediting authority equivalent to the TGA.
- Pharmacists sourcing starting materials from a third-party supplier, including a wholesaler, are responsible for confirming the manufacturer has an appropriate licence, certificate or equivalent accreditation.

- If a certificate of analysis (C of A) is not available for an ingredient or not provided by the manufacturer, or the pharmacist has concerns about the authenticity of the C of A, the pharmacist should have the ingredient tested by a laboratory holding appropriate credentials for testing (e.g. accredited by the National Association of Testing Authorities (NATA) or licensed by the TGA), to confirm its suitability for compounding.

Further information about starting materials is available in the current edition of the *Australian Pharmaceutical Formulary and Handbook*. State, territory and Commonwealth entities may also publish relevant information (e.g. local health departments and premises regulators).

Guidance

4.1 Risk assessment process for facilities and equipment

The compounding pharmacist and the person responsible for the operation of the premises where medicines are compounded must conduct a risk assessment to determine whether the facilities and equipment are suitable for the type of medicines that are to be compounded (e.g. veterinary medicines or cytotoxic medicines). Compounding must not take place if the facilities and equipment are unsuitable and/or unsafe.

If a compounding pharmacist identifies deficiencies in the facilities and/or equipment, they must notify the person responsible for the premises to implement corrective action that ensures legal and safe practice.

4.2 Starting materials

A pharmacist must obtain the necessary evidence to demonstrate that all ingredients comply with pharmacopoeial standards or other relevant standards and are safe for human use (or animal use for veterinary medicines) before using the ingredient in a compounded medicine.

4.3 Supervision of support staff

When engaging the support of ancillary staff in the compounding process, it remains the supervising pharmacist's responsibility to:

a. ensure support staff have the appropriate education, training and/or experience for the specific compounding activities being carried out,
b. assign duties commensurate with the individual's education, training and/or experience,
c. conduct a risk assessment for the medicine being compounded, and ensure that all risks are appropriately managed,
d. ensure all weighing and measuring is conducted appropriately,
e. ensure all packaging and labelling of the compounded medicine is appropriate,
f. ensure the medicine has been compounded in accordance with formulas from a reputable reference, and in a way that ensures the safety, quality and efficacy of the medicine,
g. ensure that compounding procedures have been documented appropriately,
h. approve the supply of the medicine, whether prescription or over the counter, to the patient, and
i. counsel and ensure the patient (or in the case of an animal patient, the owner) is given relevant information about the compounded medicine.

A pharmacist must not devolve their professional responsibilities to a person undertaking a task under their supervision.

The obligations of pharmacists in relation to supervising and training staff are set out in guideline 12 *Dispensary assistants/dispensary technicians and hospital pharmacy technicians* of the Board's *Guidelines for dispensing of medicines*.

5 Formulation considerations

Rationales for the formulation of compounded medicines should be sought from reputable references such as the *Australian Pharmaceutical Formulary and Handbook*, international pharmacopoeial standards and peer reviewed journals.

Some peer-reviewed published information about compounding medicines may state that commercial medicines can be modified (e.g. adding a flavour) or used as an ingredient (e.g. using crushed tablets to make an oral liquid preparation for paediatric use). In other cases, the use of a commercial medicine in compounding a medicine will not be suitable and a formulation may need to be developed.

Confirming the rationale for a formulation may require collaborating with the prescriber to reach agreement on the suitability of the medicine for the intended patient. This is important when compounding medicines for both human and animal patients. Development of a formulation should be based on published and reputable information, not testimonials or impressions.

The suitability of a formula will also be determined by the applicable expiry date of the compounded medicine to ensure it can be used in the timeframe that meets the patient's needs (e.g. if the use of a preservative is appropriate and supports assigning a longer expiry date). Refer to *Guideline 5 Assigning expiry dates to compounded medicines* for information on assigning a suitable expiry date.

There are several factors to consider when developing a formulation, the Board has provided guidance on some of these below.

Guidance

5.1 Formulations for which precedents do not exist

A pharmacist is required to use sound judgement based on up-to-date clinical and pharmaceutical knowledge and document a risk assessment before deciding whether to compound a medicine for which there is no formulation precedent in a reputable reference and for which there is inadequate published safety, efficacy, pharmacokinetic or clinical data.

Examples of such medicines could include (but are not limited to):

a. preparations containing hormones, or
b. substances not approved in Australia for therapeutic use.

If a medicine is compounded under these circumstances, the evidence supporting the decision should be documented and referenced in the risk assessment. The pharmacist must also ensure that the patient has been advised that the compounding has taken place under these circumstances. In the absence of documented evidence, pharmacists must not compound such medicines.

See the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook* for additional information on risk assessments.

5.2 Quantity to be supplied

The quantity of compounded medicine to be supplied should be a single unit of issue for the treatment of a particular patient. A single unit of issue should be the quantity that the patient requires for the treatment period determined by the prescriber and that ensures a quality and efficacious medicine. For example, if a medicine will expire after 30 days, a quantity of the medicine providing treatment for 60 days should not be compounded and supplied to the patient. If the quantity is not specified, this must be confirmed with the prescriber.

Note for animal patients:

In the case of compounded veterinary medicines, a pharmacist may supply more than a single unit of issue of a medicine when supplied in response to instructions from a veterinarian (e.g. supply for multiple animals such as a herd).

5.3 Modification of commercial medicines

If modification of a commercial medicine, not in accordance with the manufacturer's instructions, is prescribed or requested, the modification should only occur:

a. if the circumstances for compounding the medicine are appropriate (refer to *Guideline 1 – When to compound medicines*),
b. if details of the modified medicine including its stability and formulation are available
c. after a risk assessment that supports the modification has been documented, and
d. after communication with the prescriber has taken place if the modification is requested by the patient,

The modification must be recorded in the patient medication record and endorsed on the prescription and duplicate (if prescribed).

For more information see the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook* for further information.

5.4 Risk assessment process for compounded medicines

Pharmacists who compound medicines (for animals or humans) must have appropriate risk management processes in place to manage risks associated with the compounded medicine. Risks may be related to the patient, product, premises or personnel.

Risk assessment and management processes must align with practice standards and guidelines, and the standards set by relevant regulatory bodies at the Commonwealth and state and territory level. A risk assessment should be documented with each request for a compounded medicine (including repeats) and must consider any risks specific to the individual patient.

For more information on risk assessment, refer to the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Note for animal patients:

Species and breed related factors should also be considered when compounding medicines for animals. Additionally, if compounding a medicine for a food producing animal species needs, risks associated with trade, public health and tissue residues need to be considered. The patient-specific risk assessment may be undertaken in conjunction with the veterinarian requesting the medicine.

5.5 Consistency of supply

If requested to compound a medicine that has been previously compounded by another pharmacist and/or at another pharmacy, the pharmacist must take reasonable steps to assure themselves that the requested medicine has been compounded consistently with previous supplies by using a formula is as close as possible to those used previously unless there are quality or safety concerns about the previous compounding.

Changing the formula from that of previous supplies could result in changes to the clinical effect of the medicine and have consequences for the patient. Consistency in formula is particularly important for high-risk medicines such as those with a narrow therapeutic index, or for modified-release preparations.

Pharmacists are reminded of their professional obligations to ensure the safety of the patient by ensuring the patient can access information such as the ingredients in their compounded medicine and should not have 'proprietary' or 'secret' formulas or ingredients.

See *Risk assessment* in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook* for further information.

6 Assigning expiry dates to compounded medicines

The *Australian Pharmaceutical Formulary and Handbook* provides guidance on assigning an appropriate expiry date (refer to *Definitions*) for specific dosage forms and states:

- for non-sterile medicines, expiry dates should be based on the guidance provided in the *Australian Pharmaceutical Formulary and Handbook*, the USP-NF <795> or other reputable guidance that will achieve at least an equivalent outcome, and
- in the case of sterile medicines, expiry dates should be based on the guidance provided in the *Australian Pharmaceutical Formulary and Handbook*, the USP-NF <797> or other reputable guidance that will achieve at least an equivalent outcome.

Guidance

Expiry dates of compounded sterile injectable medicines

Due to the risks associated with compounded sterile injectable medicines, it is recommended that pharmacists assign an expiry date of no more than 24 hours (when stored under the recommended storage conditions for the particular medicine) from the time of compounding. A longer expiry date may result in:

a. increased likelihood of microbial growth in the compounded medicine,
b. greater chemical instability of the compounded medicine which may result in reduced therapeutic activity, or greater toxicity caused by degradation products, and
c. increased likelihood of dose administration errors associated with the compounded medicine, for example an infusion bag that was compounded before a dose change, being incorrectly administered to a patient.

An expiry date of longer than 24 hours may be assigned to a compounded sterile injectable medicine only if the pharmacist meets all the necessary conditions outlined in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

A pharmacist must provide advice about the compounded sterile injectable medicine, including the in-use expiry during which administration of the medicine to a particular patient should be completed, when supplying it to the patient and/or the person administering the medicine (refer to Guideline 15 *Counselling and information for patients*).

7 Batch preparation

When considering whether to compound a batch, a pharmacist must ensure that the batch compounding is in accordance with legislation (e.g. a prescription has been received for individual named patients when required by legislation). Refer to the background document or Therapeutic Goods legislation for further information.

Information in relation to batch preparation can be found in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Guidance

Batch preparation of compounded medicines is discouraged due to the higher risks, e.g. a compounding error or contamination potentially affecting a larger number of patients (human or animal).

As for compounding a single unit, a pharmacist must conduct and document a risk assessment before deciding to compound a batch. Refer to *Risk assessment* in the *Compounding* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Pharmacists must ensure they have sufficient evidence that appropriate processes are in place and have been followed to effectively manage any additional risk associated with batch preparation (also refer to Guideline 12 *Documentation*).

8 Managing risks that may lead to injury

Pharmacists are legally obligated to comply with occupational health and safety standards in accordance with relevant professional practice standards and these guidelines. This includes benchmark and routine health monitoring of staff involved in compounding medicines containing cytotoxic or other hazardous chemicals such as hormones.

Guidance on workplace safety when preparing sterile compounded medicines or handling hazardous substances, is published in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Guidance

When compounding medicines involves the use of substances, equipment and/or techniques that could lead to harm, everyone involved must be appropriately trained in the necessary precautions that support safe practice.

9 Documentation

Pharmacists are required to document the preparation of compounded medicines in accordance with state, territory and Commonwealth legislation. For example, when using ingredients that are Schedule 8 medicines, maintenance of records must be in accordance with state and territory legislation.

Practice standards and guidelines, and the *Compounding* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook* also set out documentation requirements including records of compounding.

Pharmacists are legally obligated to make available to any authorised person (under relevant jurisdictional law) documentation and other evidence to demonstrate the compounding has been carried out in accordance with all legal requirements, guidelines and practice standards and the applicable guide/standard (e.g. PIC/S, USP) listed in the *Australian Pharmaceutical Formulary and Handbook.*

Guidance

Appropriate documentation is required which:

a. justifies the decision whether to compound the medicine including the risk assessment
b. supports the quality assurance of compounding activities within the pharmacy,
c. accounts for the use of ingredients that are subject to abuse or diversion,
d. enables the recall of compounded medicines including when medicines are compounded from ingredients that are subject of a TGA recall, and
e. supports routine reporting of adverse events.

Documentation must be maintained clearly demonstrating that all individuals have met their responsibilities of compliance with legislation, practice standards and procedures relevant to compounding.

10 Packaging and labelling requirements

Pharmacists are legally obligated to package and label compounded medicines in accordance with the *Poisons Standard* and relevant state and territory legislation.

Relevant practice standards, guidelines and the information published in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook* sets out the professional obligations for pharmacists in relation to packaging and labelling compounded medicines.

Guideline 7 *Labelling of dispensed medicines* of the Board's *Guidelines for dispensing of medicines* also provides additional guidance for labelling compounded medicines.

(Note: the Poisons Standard is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).

Guidance

Guideline 7 *Labelling of dispensed medicines* of the Board's *Guidelines for dispensing of medicines* states that compounded medicine labels should include:

- the name and quantities or concentrations of each active ingredient (especially if a formula other than a standard pharmacopoeial formula is used) or the pharmacopoeial or APF name ,
- the name and strength of any added preservatives,
- the name of the formula as described in a standard pharmacopoeial reference book (where applicable)
- the dose form and quantity supplied, and
- the patient's name or, in the case of an animal, the owner's name and the kind of animal.

If it is not possible to fit all the details of a non-pharmacopoeial formula on the dispensing label, a copy of the formula should also be provided to the patient.

An ancillary label with the words 'This product has been compounded by the pharmacist', should also be affixed to the primary medicine container. Refer to the *Australian Pharmaceutical Formulary and Handbook* for a list of cautionary advisory labels (CALs).

11 Counselling and provision of information on compounded medicines

Guideline 8 *Counselling patients about prescribed medicines* of the Board's *Guidelines for dispensing of medicines* states that pharmacists should ensure that every patient or their agent is offered counselling and relevant consumer medicine information whenever a compounded medicine is supplied. As consumer medicines information leaflets are not usually available for compounded medicines, alternative written information may be required.

Guidance

Verbal counselling, including written information where appropriate or required, should be provided by the pharmacist to help communicate the following counselling points to facilitate the safe and effective use of the compounded medicine:

a. an explanation of why a compounded medicine is being supplied, and how this differs to a:
    i. medicine on the ARTG, which meets TGA requirements, or
    ii. registered veterinary chemical product that meet APVMA requirements,
b. instructions on how and when to take, administer or apply the medicine (e.g. advising the person administering the medicine to wear gloves if the medicine is a skin irritant),
c. the appropriate storage requirements and expiry date of the medicine,
d. the side-effect profile of the medicine, any contraindications and any other specific counselling points that would normally be contained in a written consumer medicines information leaflet
e. information on appropriate disposal
f. how to report adverse events, and
g. any other information that would be appropriate.

Some patients may require additional information about the ingredients, for example:

a. a participant in competitive sport who may require further information about the active ingredients to understand if they are permitted or prohibited in their sport, or
b. a patient who has a known allergy or sensitivity to an excipient.

Pharmacists must make every reasonable attempt to address any queries or concerns that a patient or their agent has, to assist them in the proper and safe use of the compounded medicine.

The Board's *FAQs for pharmacists on the compounding of medicines* provide scenarios where pharmacists are responsible for providing counselling to the patient.

12 Reporting of adverse events

As with any medicine, the use of compounded medicines may be associated with adverse events. While it may be difficult to determine whether a particular medicine has caused an adverse event in an individual case, reporting helps accumulate evidence of the possible adverse effects of an ingredient or medicine.

Further information on reporting suspected adverse events can be found in *Quality Assurance* in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Guidance

Pharmacists should report all suspected adverse events to compounded medicines to:

a. the TGA and the prescriber for suspected adverse events in humans, and
b. the veterinary surgeon who issued instructions for the compounded medicine for suspected adverse events in animals.

This reporting requires appropriate documentation and recording of adverse events.

13 Supporting informed patient choice

The *Code of conduct for pharmacists* supports good practice and therefore applies to the supply of all medicines including compounded medicines. The code states:

Providing good care includes that you:

e) recognise and respect the rights of patients to make their own decisions about their current and future healthcare.

This includes when offering patients information and services for their convenience e.g. providing the location of a particular service or offering to hold prescriptions at the pharmacy for safe keeping. Patients are entitled to hold their prescription (or a detailed copy) if they choose.

Providing all relevant information about how medicines or services can be accessed enables informed patient choice.

Guidance

Pharmacists must not make arrangements that restrict a patient's choice in where to access compounded medicines, for example by receiving prescriptions for compounded medicines direct from the prescriber without the patient giving informed consent.

Pharmacists may retain prescriptions for subsequent dispensing if the patient has provided consent.

To support patient choice, a copy of the formula for their compounded medicine must be provided to the patient when requested. A copy of the formula should list:

- all active ingredients and their strengths, and
- all inactive ingredients.

14 Advertising

Compounded medicines for human patients are subject to the advertising provisions of the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods Advertising Code* and any relevant state and territory legislation. Compounded medicines that are Schedule 3 (but not listed in Appendix H of the *Poisons Standard*), Schedule 4 and Schedule 8 cannot be advertised to the public. Advertisements for compounded medicines that can be advertised require pre-approval by the Secretary of the Department of Health if they are to be placed in certain types of media, including (but not limited to) billboards, newspaper, magazines, and television (for further information about which types of media require pre-approval, visit www.tga.gov.au).

The National Law sets out legal obligations in relation to the advertising of regulated health services, which includes compounding services. The Board's Guidelines for advertising a regulated health service (advertising guidelines) provide guidance on advertising regulated health services in accordance with the National Law. The advertising guidelines define advertising as including, but not limited to, all forms of verbal, printed or electronic public communication that promotes a regulated health service provider to attract a person to the provider (practitioner or business). This can include advertising via internet websites and social media platforms.

The advertising hub on the Ahpra website includes details of the laws and other guidance about how to advertise, resources to help advertisers understand their advertising obligations and to check their advertising is correct.

Compounded medicines for animal patients are subject to the advertising provision of the AgVet Code.

Guidance

For medicines that can be advertised (generally, medicines that are unscheduled, Schedule 2 or Schedule 3 and included in Appendix H of the *Poisons Standard*), pharmacists must be able to support any promotional claims with acceptable evidence when advertising a specific formula or medicine (refer to section 4 *What are the advertising requirements of the National Law* in the Board's *Guidelines for advertising a regulated health service*).

15 Reference texts and other sources of information relevant to compounding

The Board's *Guidelines on practice-specific issues – Guideline 1* (List of reference texts for pharmacists) states that all pharmacists are required to have ready access to the current edition of the *Australian Pharmaceutical Formulary and Handbook*. The *Australian Pharmaceutical Formulary and Handbook* is referenced throughout these guidelines.

Other suitable reference texts and sources of information on compounding can be found in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

(Note: Pharmacists can access relevant state, territory and Commonwealth legislation at www.comlaw.gov.au).

Guidance

Compounding pharmacists must have access to professional practice standards, guidelines, legislation and any other contemporary works of professional reference relevant to their area of compounding. These should be in the form of a published document (hard copy) or via electronic means, such as a computer.

Suitable resources on the compounding of animal medicines should be available to pharmacists involved in compounding animal medicines. Given the complex differences between animal species, collaboration with a veterinary surgeon may also be required to assure the pharmacist that the compounded medicine is safe and appropriate for a particular animal patient.

Definitions

Adverse event (for the purpose of these guidelines, based on the definitions provided by the Therapeutic Goods Administration and the World Health Organisation), is any untoward medical occurrence in a patient administered a medicine, but which does not necessarily have a causal relationship with that medicine. It is thought to relate to the medical management of a patient, in contrast to the complications of disease. Medical management includes all aspects of care, including diagnosis, treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. An *adverse effect* (or side effect) is one type of adverse event, which specifically relates to the treatment of a patient.

Approved and/or registered premises means a pharmacy premises established and operating under relevant state and territory legislation and is not limited to premises approved under section 90 of the National Health Act 1953 (the Act).

Batch means a quantity of a medicine that is uniform in composition, method of manufacture and probability of chemical or microbial contamination, and is made in one cycle of manufacture and, in the case of a medicine that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

Batch preparation is the creation of a batch of multiple units of issue of a medicine.

Commercial medicine means for the purpose of these guidelines, a medicine that can be accessed in Australia through any pathway for the lawful supply of medicines. This includes medicines entered on the ARTG and medicines accessed through other pathways such as s19A, Special Access Scheme and others. For animal patients this includes medicines entered on the APVMA PubCRIS database. A medicine compounded by a pharmacist under the relevant exemptions to therapeutic goods legislation is not considered a commercial medicine for the purposes of these guidelines. The *Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists* sets out the pathways for lawful supply of medicines in Australia including medicines exempt from entry on the ARTG.

Complex compounding requires or involves special competencies, equipment, processes and/or facilities. Examples include sterile preparations, preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxics or some hormones) and micro-dose single-unit dosage forms containing less than 25mg (or up to 25 per cent by weight or volume) of active ingredient. Refer to the section *Compounding* in the current edition of the *Australian Pharmaceutical Formulary and Handbook* for further examples and information.

Compounding (medicines for **human patients**) means for the purpose of these guidelines, the extemporaneous preparation and supply of a single ‘unit of issue’ of a therapeutic product intended for supply for a specific patient in response to an identified need. The practice of compounding is classified in these guidelines as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding. Compounding/manufacturing may also be defined in state and territory legislation.

Compounding (medicines for **animal patients**) means for the purpose of these guidelines, the extemporaneous preparation and supply of a therapeutic product as instructed by a veterinarian. The practice of compounding is classified in these guidelines as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding. Compounding/manufacturing may also be defined in state and territory legislation.

Co-regulatory jurisdiction means a participating jurisdiction in which the National Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8. Queensland and New South Wales are co-regulatory jurisdictions.

Dispensing is the preparation, packaging, labelling, record keeping and transfer of a prescription drug to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient (see Guideline 1 *The dispensing process* in the Board's *Guidelines for dispensing of medicines*).

Expiry date is the final date the compounded medicine can be used. After the expiry date has passed, the compounded medicine should not be used or continue to be used. Refer to the section *Compounding* in the current edition of the *Australian Pharmaceutical Formulary and Handbook* for further information.

Scope of practice means the professional role and services that an individual health practitioner is educated and competent to perform.

Simple compounding routinely involves the compounding of medicines from formulas published in reputable references such as the *Australian Pharmaceutical Formulary and Handbook* (excluding the preparation of sterile or hazardous medicines from these formulas, which is considered complex compounding), or using other formulas for which information confirming quality, stability, safety, efficacy and rationality is available. Simple compounding excludes any compounding that meets the definition of complex compounding.

Unit of issue means a quantity of a formulation to be supplied for the treatment of an individual patient.

Board references

Pharmacy Board of Australia *Guidelines for dispensing of medicines*, including:

- Guideline 4 *Internet, mail-order dispensing and other indirect supply of medicines*
- Guideline 7 *Labelling of dispensed medicines*
- Guideline 8 *Counselling patients about prescribed medicines*
- Guideline 12 *Dispensary assistant/dispensary technicians and hospital pharmacy technicians*

Pharmacy Board of Australia *Guidelines for proprietor pharmacists*

Pharmacy Board of Australia *Guidelines for advertising a regulated health service*

Pharmacy Board of Australia *Guidelines on practice-specific issues*

Pharmacy Board of Australia *Code of conduct for pharmacists*

Pharmacy Board of Australia *Registration standard: Continuing professional development*

Ahpra *A guide for practitioners: Notifications in the National Scheme*

Review

Date of issue: XXX

In effect from: XXX

Date of review: XXX

These guidelines will be reviewed at least every five years.

From XXX, these guidelines replace *Guidelines on compounding of medicines* published 28 April 2015.

Attachment B

Summary of proposed changes to the Guidelines on compounding of medicines

May 2023

Summary

The table below summarises the changes between the current *Guidelines on compounding of medicines* and the draft revised *Guidelines on compounding of medicines*. The table is not intended to provide a detailed explanation of all the changes but to provide a reference to the guidelines where content has changed and/or moved. Pharmacists are required to reflect on their practice when guidelines and other relevant documents are updated to ensure appropriate compounding practices.

In summary, the key proposed changes are:

1. additional content to provide more guidance on when it may be appropriate to compound a medicine
   - consideration of other pathways to access medicines
2. removal of information that duplicates essential references
   - removal of detailed information in relation to setting expiry dates for sterile injectables
3. separating context from Board guidance where possible
4. reorganised content to reduce duplication and make the sequence of information more logical, and
5. minor changes to refine and clarify wording and expression throughout the guidelines.

Current Guidelines on compounding of medicines	Draft revised Guidelines on compounding of medicines
Who needs to use these guidelines?	**Who needs to use these guidelines?**
Introduction	**Introduction** • Revised to outline the responsibilities of pharmacists involved in compounding e.g. compliance with legislation, supported by evidence • Added what the term 'patient' means in the guidelines
Relevant legislation and practice standards	**Relevant legislation, quality standards and practice standards** • Revised to include reference to PIC/S and USP, AgVet Code, GMP and quality standards as set out in Therapeutic Goods Act • Added a note (3) to cover any additional documents that may be published in the future
What happens if I do not comply with these guidelines?	**What happens if I do not comply with these guidelines?**
Guidelines	**Guidelines**
1 Instruction to compound a medicine	**1 When to compound medicines** • Quantity to be compounded moved to new guideline 4.2
	1.1 Considerations before compounding a medicine • provides additional information on when it is appropriate to compound medicines as well as other legal pathways to access medicines that should be considered • definition of a "commercial medicine" added, which includes medicines on the ARTG and medicines accessed through other pathways such as the Special Access Scheme, this has changed from the previous definition which only included medicines on the ARTG • differences when compounding for animal patients clearly highlighted

Current Guidelines on compounding of medicines	Draft revised Guidelines on compounding of medicines
	1.2 Obligations when a prescribed or requested medicine cannot be compounded
2 Appropriate circumstances for compounding medicines	Moved to guideline 1.1
3 Competence to undertake 'simple compounding'	**2 Competence to undertake compounding** • Combines the information from guidelines 3 and 4
4 Competence to undertake 'complex compounding'	**2 Competence to undertake compounding**
4.1 Professional practice profile for pharmacists undertaking complex compounding	Removed - Propose to no longer publish a professional practice profile, guideline 2 still refers pharmacists to create a personalised professional practice profile.
4.2 Demonstrating competence to undertake complex compounding	Moved to guideline 2 Competence to undertake compounding
5 Veterinary medicines	Separate guideline removed - Information moved into other guidelines where appropriate. Where guidance differs for animal patients, it is clearly stated.
6 Formulation considerations	**5 Formulation considerations** Information has been moved to: • guideline 1.1 Considerations before compounding a medicine • new guideline 5.5 Consistency of supply • guideline 11 Counselling and information for patients • PII information amended and moved to introduction
6.1 Formulations for which precedents do not exist	5.1 Formulations for which precedents do not exist
6.2 Compounding of sterile injectable medicines	**6 Assigning expiry dates to compounded medicines** • Most of the detailed information for sterile injectables has been removed as it duplicates information in the current edition of the APF. Guidance for setting expiry dates of compounded sterile injectable medicines is still included and pharmacists are referred to APF for guidance on setting expiry dates of longer than 24 hours • Information on PIC/S, USP and notifications moved to Introduction

Current Guidelines on compounding of medicines	Draft revised Guidelines on compounding of medicines
	• Guidance on choosing PIC/S or USP when compounding sterile medicines moved to guideline 3.1 Sterile medicines • Self-assessment and audit guidance moved to guideline 3 Quality assurance
6.3 Manipulation of products in accordance with manufacturer's instructions	Moved to the beginning of the guidelines
6.4 Modification of commercially available products	5.3 Modification of commercial medicines
6.5 Risk assessment process for compounded products	5.4 Risk assessment process for compounded products • Added that a risk assessment should be completed and documented with each request for a compounded medicine
6.6 Batch preparation	**7 Batch preparation** • emphasised the requirement to ensure that the batch compounding is in accordance with legislation (e.g. have a prescription for individual named patients when required by legislation) • examples of batch compounding removed
7 Supervision of appropriately trained staff	Moved to guideline 3.2 Supervision of support staff
8 Facilities, working environments and equipment	**4 Facilities, equipment, working environments, materials and support staff**
8.1 Additional requirements relating to facilities, working environments and equipment applicable to complex compounding	Moved to guideline 4 Facilities, equipment, working environments, materials and support staff
9 Managing risks that may lead to injury	**8 Managing risks that may lead to injury** • Guidance made more general in nature, noting that penetration of the skin is not the only risk
10 Raw materials	**4 Facilities, equipment, working environments, materials and support staff** • Information on raw materials (starting materials) moved to guideline 4

Current Guidelines on compounding of medicines	Draft revised Guidelines on compounding of medicines
11 Quality standards	**3 Quality assurance** • Information on quality standards moved to introduction
12 Documentation	**9 Documentation**
13 Reporting of adverse events	**12 Reporting of adverse events**
14 Packaging and labelling requirements	**10 Packaging and labelling requirements** • Reference to Therapeutic Goods Order (TGO) No.69 removed as no longer current. Relevant TGOs now referenced in the background document
15 Counselling and information for patients	**11 Counselling and provision of information on compounded medicines**
16 The patient's right to choose where to access all types of compounded medicines	**13 Supporting informed patient choice**
17 Advertising	**14 Advertising**
18 Reference texts and other sources of information relevant to compounding	**15 Reference texts and other sources of information relevant to compounding**
Definitions	**Definitions** • Compounding for human patients separated from compounding for animal patients
General	Minor wording changes throughout document to improve readability and reduce complexity of document. Separation of context and Board guidance where possible

Attachment C

Information for members of the public about compounded medicines

We have prepared this document to help you understand how compounded medicines are different to other medicines you may receive. This may help you understand the purpose of our consultation paper and to provide feedback on the Board's guidelines for pharmacists on the compounding of medicines.

What is compounding?

Compounding is when a pharmacist makes a medicine to meet the unique needs of a patient (either human or animal) when available medicines do not meet those needs. Reasons a pharmacist may need to compound a medicine include:

- you have an allergy to an ingredient in the available medicines
- the medicine you need is temporarily unavailable or no longer made
- you need the medication in a form that is different to the available medicine, for example if you need a liquid instead of a tablet.

How can I get a compounded medicine?

A pharmacist may compound a medicine if:

- they receive a prescription from a doctor or other health practitioner who can write a prescription (the prescriber), or
- requested by a person for a medicine that does not require a prescription, or
- they get an instruction from a veterinarian (for an animal patient), or
- there is a particular need to have the medicine available for use in a hospital.

On each occasion, the pharmacist must determine if it is appropriate and safe to compound and supply the medicine. If an alternative option is best, the pharmacist will discuss this with you and the prescriber.

Are compounded medicines different to other medicines?

Most medicines go through an assessment and approval process before they can be supplied in Australia. This is to ensure that the medicines supplied meet the required quality and safety standards and have evidence of being effective treatments.

A compounded medicine, which is prepared by a pharmacist to meet the unique needs of a patient, is not required to undergo the assessment and approval process, but it must be of good quality, safe and effective.

Is a compounded medicine safe?

Before compounding a medicine for you, the pharmacist needs to ensure there is evidence that the formula of the compounded medicine will provide a medicine that is safe, effective and of high quality. The pharmacist must also ensure the ingredients they use are of acceptable quality and that the pharmacy is appropriately set up and has the right equipment to compound the medicine. If unable to provide these assurances, the pharmacist will discuss other suitable options with you and the prescriber.

Are all pharmacists able to compound medicines?

After completing their qualification and training, pharmacists are competent to compound some medicines. Some other medicines are more complex, requiring pharmacists to complete further education and training. You should ask your pharmacist if they have completed the appropriate education and training and have recent experience to compound the medicine for you.

When can't a pharmacist compound a medicine?

A pharmacist cannot compound a medicine if:

- it would be the same as a medicine that already exists and is available to supply to you, even if it would be cheaper
- the pharmacy does not have the right equipment to compound it safely
- there is no evidence that it is a safe and effective treatment for you.

If compounding the medicine requires special skills, education and training, which the pharmacist hasn't completed, or requires equipment that is not available at the pharmacy, you may be referred to another pharmacy.

Can I choose where to get my compounded medicine?

You have the right to choose which pharmacy you get your compounded medicine from. But, if the medicine is complex (requires special equipment, facilities and/or training), not all pharmacies may be able to supply the medicine. To find a pharmacy that can compound your medicine, you can ask your pharmacist or health practitioner, or search online.

What can I expect from my pharmacist when I get my compounded medicine?

Before compounding your medicine, the pharmacist may need to ask you questions to make sure that a compounded medicine is the best option for you.

The pharmacist should offer you information about your medicine including:

- an explanation of why a compounded product is being supplied and how it is different to other medicines
- instructions on the correct use of the medicine
- the appropriate storage requirements and expiry date of the medicine
- the possible side effects of the medicine, how to manage them and who you should tell about them
- any situations where it is inappropriate to use the medicine, and
- any other specific information that helps you use the medicine safely and effectively.

If you need additional information about the ingredients, for example, due to an allergy or sensitivity or to confirm if the medicine is appropriate to use if you participate in competitive sports, you should ask your pharmacist.

When should I talk to my health practitioner/s?

If you have any questions about your medicine, including how to use it, about its safety or why a compounded medicine is best for you, talk to your pharmacist and the prescriber.

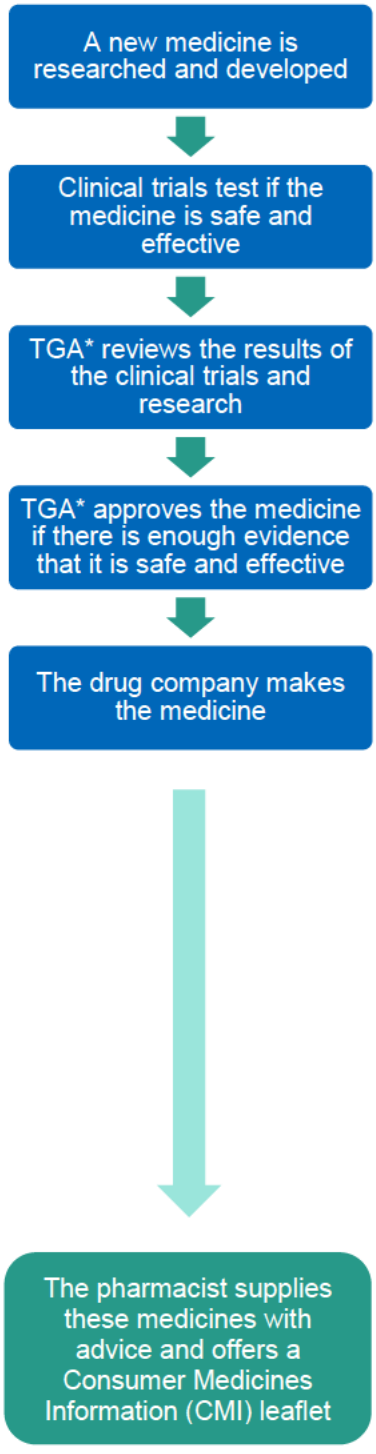
Who approves medicines in Australia?

The Therapeutic Goods Administration (TGA) approves medicines (for humans) for supply in Australia. The TGA works to make sure the benefits of a medicine are greater than the risks from the medicine such as side effects. For more information on the TGA and how medicines are regulated in Australia visit the TGA Consumers webpage.

Veterinary medicines are evaluated and registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

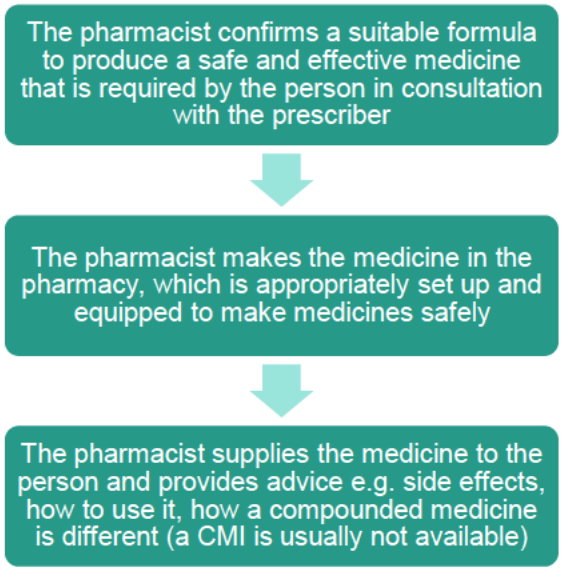
How most medicines for humans are made

*The Therapeutic Goods Administration (TGA) approves medicines for supply in Australia



For animal medicines, a similar process is followed with review and registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

How medicines are compounded and supplied by pharmacists



Attachment D

Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists

This document contains background information on the regulation of supply and manufacture of medicines[1] including compounding of medicines by pharmacists, which is set out in relevant legislation and administered by the responsible entities. It provides an explanation of the regulatory environment in which the Pharmacy Board of Australia's (the Board's) *Guidelines on compounding of medicines* should be applied by pharmacists when compounding medicines.

Compounding medicines for humans

Therapeutic goods legislation

The Therapeutic Goods Act 1989 (Cth)[2] (the Act) sets out the legal requirements for the import, export, manufacture (which includes compounding of medicines by pharmacists) and supply of therapeutic goods in Australia.

The *Therapeutic Goods Act 1989* (Cth) is generally given effect in all states and territories by complementary legislation, except in Western Australia.

The Act details the requirements for listing, registering or including medicines, medical devices and biological products on the Australian Register of Therapeutic Goods (ARTG)[3] and many other aspects of the law including advertising, labelling, and product appearance. It also sets out the requirements for licensing manufacturing sites in Australia.

The Act is supported by the Therapeutic Goods Regulations 1990[4], and various Orders and Determinations that provide further details of matters covered in the Act.

Therapeutic goods orders (TGOs) are approved under section 10 of the *Therapeutic Goods Act 1989.* A TGO specifies an Australian standard for therapeutic goods or particular types of therapeutic goods (for example, prescription medicines). TGOs specify requirements relating to matters such as quality, procedures to be carried out in the manufacture of goods, labelling and packaging.

In addition to TGOs, monographs in the British Pharmacopoeia (BP), European Pharmacopoeia (Ph Eur), and United States Pharmacopoeia-National Formulary (USP) are defined in the *Therapeutic Goods Act 1989* to be 'default standards' and apply to therapeutic goods that are the subject of the relevant monographs.

Refer to Appendix A for a summary of the pathways for lawful supply of medicines in Australia, including medicines exempt from entry on the ARTG and TGOs applicable to compounded medicines.

[1] Medicine is defined by TGA as meaning therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human

[2] Available at www.comlaw.gov.au/Series/C2004A03952

[3] Available at www.tga.gov.au/industry/artg.htm

[4] Available at www.comlaw.gov.au/Series/F1996B00406)

Exemptions for pharmacists to compound medicines

The *Therapeutic Goods Act 1989* requires:

a. therapeutic goods (including medicines) to be entered on the Australian Register of Therapeutic Goods (ARTG)[5] before they can be supplied in Australia, unless exempt, authorised or otherwise approved, and

b. manufacturing of medicines in Australia to be in compliance with the Guide to Good Manufacturing Practice for Medicinal Products[6] and to take place in premises licensed by the Therapeutic Goods Administration (TGA), unless exempt.

The Therapeutic Goods Regulations 1990[7] 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 or that are medicinal cannabis products) 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.

Despite the exemptions listed above, compounded medicines are not exempted from all requirements of the *Therapeutic Goods Act 1989* (Cth). Compounded goods are required to comply with all relevant TGOs (except for TGOs that are expressed as not applying to these goods) and relevant default standards. Similarly, advertising requirements in the *Therapeutic Goods Act 1989* (Cth) apply to goods not on the ARTG, including compounded medicines.

[5] Available at www.tga.gov.au/industry/artg.htm
[6] Available at www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm
[7] Available at www.comlaw.gov.au/Series/F1996B00406)

Additional requirements may apply to the supply of compounded medicines (for example, pharmacists may only compound a medicinal cannabis product with a prescription based on approvals under either the Special Access Scheme or Authorised Prescriber pathway). Refer to the relevant legislation for further information.

This information is subject to possible change with amendments to TGA legislation. Refer to www.tga.gov.au for further information.

Compounding veterinary medicines

The *Agricultural and Veterinary Chemicals Code* (AgVet Code) exempts medicines from registration by the APVMA when compounded by a pharmacist in accordance with the instructions of a veterinary surgeon. To compound a medicine for animal use, the pharmacist must have received instructions from a veterinary surgeon.

While this instruction is not required to be in writing, the Australian Pesticides and Veterinary Medicines Association (APVMA) advises that best practice would indicate the provision of precise written instructions to evidence any transaction. Where state or territory requirements exist regarding the instructions required from a veterinary surgeon for supply of a compounded veterinary product, these must also be complied with. Penalties may be applied in the case of non-compliance.

Obligation to meet relevant legislation

When compounding, in addition to the legislation outlined above, pharmacists have obligations to comply with requirements regarding issues such as advertising and workplace/premises under other relevant state, territory and Commonwealth legislation.

Premises regulation

Each state and territory has separate legislation, guidelines and/or requirements for pharmacy ownership and regulation of premises, including inspections.

Pharmacists must comply with all legislation relevant to the practice of pharmacy and requirements for pharmacy premises in their jurisdiction.

The state/territory pharmacy premises regulatory authority or responsible body may conduct audits/inspections of approved and/or registered premises and their associated facilities.

These state/territory-based authorities cooperate closely with the Board to ensure the safety of the Australian community and assist in resolving matters such as non-compliance with the Board's *Guidelines on compounding of medicines* and other guidelines set by the Board and the authorities.

Published: xx

Note: the information provided in this background information sheet was considered to be true and correct at the time of publication.

Appendix A

This appendix sets out pathways for supply of medicines (for humans) in Australia, relevant exemptions to therapeutic goods legislation that provide for pharmacists to compound medicines not included in the ARTG, the requirement for a licence under Part 3-3 of the Act, and the Therapeutic Goods Orders applicable to compounded medicines.

(*Note: This is not a comprehensive document of all legislative requirements. For further information refer to www.tga.gov.au/regulation-basics.)*

Lawful supply of medicines in Australia

The following table summarises the pathways for the supply of medicines set out in the *Therapeutic Goods Act 1989* (further information available at www.legislation.gov.au/Series/C2004A03952)

Summary	Section of the Act	TGA guidance
Approval for supply after evaluation by the TGA and registration on the ARTG Registered 'AUST R' medicines - Prescription medicines - Non-prescription medicines, including OTC pharmaceuticals and registered complementary medicines	25AB	
Approval for supply after certification by sponsor of the safety and quality and evaluation of efficacy claims by TGA, prior to listing on ARTG Listed Assessed 'AUST L(A)' medicines - complementary medicines	26AB	
Approval for supply after certification by sponsor and listing on ARTG, without prior evaluation by TGA Listed 'AUST L' medicines - complementary medicines - sunscreens	26A	
Approval for supply under specific circumstances, exemption from entry on the ARTG - Special Access Scheme Category A	18	Special Access Scheme
Approval for supply under specific circumstances, exemption from entry on the ARTG - Special Access Scheme - Experimental medicines (clinical trials) - Authorised Prescriber	19	Accessing unapproved products
Approval for supply under specific circumstances, exemption from entry on the ARTG - Medicine shortages: when medicines on the ARTG, or under evaluation by the TGA, are not available and an alternative medicine is necessary in the interests of public health	19A	Medicine shortages

Summary	Section of the Act	TGA guidance
An exemption from entry on the ARTG during a declared national emergency (these are identified in legislative instruments outlining the type of goods and any conditions on supply)	18A	-

The following table summarises the pathways set out in the Therapeutic Goods Regulations 1990 (further information available at www.legislation.gov.au/Series/F1996B00406).

Summary	Reference of Regulations	Specific item for example reference
Conditional exemptions in certain circumstances to supply medicines without entry on ARTG - licensed manufacturers supplying a hospital under contract	Schedule 5A	Item 5

Exemptions for compounded medicines

The exemptions applicable to pharmacists in the compounding of medicines are set out in the Therapeutic Goods legislation. The following table summarises the exemptions set out in the Therapeutic Goods Regulations 1990 (further information available at www.legislation.gov.au/Series/F1996B00406).

Summary	Reference of Regulations	Specific item for example reference
Exemptions to supply medicines without entry on the ARTG - Extemporaneously compounded medicines	Schedule 5	Item 6 Item 6A
Exemptions in specified circumstances to allow persons to manufacture in Australia without a GMP licence - Pharmacists, under specified circumstances	Schedule 8	Item 2 Item 3

Therapeutic goods orders applicable to compounding

The following table summarises the Therapeutic Goods Orders that may be applicable to compounded medicines depending on the circumstances (further information is available at www.tga.gov.au/therapeutic-goods-orders).

TGO Number	Name (and link) to relevant TGOs	Applies to extemporaneously compounded medicines?
TGO 91	Standard for labels of prescription and related medicines	No - provided specified conditions are met
TGO 92	Standard for labels for non-prescription medicines	No - provided specified conditions are met

TGO Number	Name (and link) to relevant TGOs	Applies to extemporaneously compounded medicines?
TGO 93	Standard for Medicinal Cannabis	Yes
TGO 95	Child resistant packaging requirements for medicines	Yes
TGO 100	Microbiological standards for medicines	Yes
TGO 101	Standard for Tablets, Capsules and Pills	Yes
TGO 106	Standard for Serialisation and Data Matrix Codes	Yes – in certain circumstances
TGO 110	Standard for Nicotine Vaping Products	Yes

Attachment E

Statement of assessment

The Pharmacy Board of Australia's (The Board's) statement of assessment against Ahpra's Procedures for the development of registration standards, codes and guidelines

Proposed revised Guidelines on compounding of medicines

The Australian Health Practitioner Regulation Agency (Ahpra) has *Procedures for the development of registration standards, codes and guidelines*, which are available at: https://www.ahpra.gov.au/Resources/Procedures.aspx

Section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) requires Ahpra to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

Below is the Board's assessment of their proposal for the draft revised *Guidelines on compounding of medicines* (the compounding guidelines), against the three elements outlined in the Ahpra procedures.

1. The proposal takes into account the objectives and guiding principles in the National Law (sections 3 and 3A) and draws on available evidence, including regulatory approaches by health practitioner regulators in countries with comparable health systems

Board assessment

The Board's proposal takes into account the National Scheme's paramount principle of protecting the public and maintaining public confidence in the safety of services provided by pharmacists.

The proposal has considered the National Scheme's objective of facilitating access to services provided by health practitioners in accordance with the public interest by providing guidance for the safe compounding of medicines to provide access to medicines for the public.

The draft revised compounding guidelines also support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way. The proposal gives clear guidance on the Board's expectation of pharmacists in relation to compounding medicines.

2. Steps have been taken to achieve greater consistency within the national scheme (for example, by adopting any available template, guidance or good practice approaches used by national scheme bodies), and the consultation requirements of the National Law are met

Board assessment

The National Law requires wide-ranging consultation on the proposed standards, codes and guidelines. The National Law also requires National Boards to consult each other on matters of shared interest. Preliminary consultation was the first step in the consultation process. The aim of the preliminary consultation was to enable the Board to test the consultation material with key stakeholders to ensure it was clear and make any amendments before proceeding to public consultation.

The Board will now ensure that there is the opportunity for broader public comment via an eight-week public consultation. This includes publishing a consultation paper on the National Board and Ahpra website and informing health practitioners and the community of the review via the National Board's electronic newsletter and social media.

The Board will consider the feedback received when finalising the draft revised compounding guidelines.

3. The proposal takes into account the principles set out in the Ahpra procedures

A. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public

Board assessment

The Board considers that this proposal is the best option for achieving public safety, high quality and professional practice and regulatory effectiveness.

The proposed revised compounding guidelines do not propose substantial changes to the current compounding guidelines or requirements for health practitioners to comply with the guidelines. The review has made the compounding guidelines clearer and easier to navigate for practitioners while ensuring that medicines are appropriately compounded.

The revised compounding guidelines complement the practice standards for pharmacists and can be applied in practice in line with the existing legislative requirements relevant to the manufacture (including compounding) of medicines.

The proposal would protect the public by making clear the expectations of a pharmacist when a medicine is compounded. The Board needs to be satisfied that pharmacists only compound medicines when it is appropriate to do so.

B. Whether the proposal results in an unnecessary restriction of competition among health practitioners

Board assessment

The proposal is unlikely to restrict competition as the proposed compounding guidelines would apply to all pharmacists who undertake compounding of medicines.

C. Whether the proposal results in an unnecessary restriction of consumer choice

Board assessment

The Board considers the proposal will not result in any unnecessary restrictions of consumer choice as the proposed revised compounding guidelines would apply to all pharmacists who compound medicines.

The proposal has the potential to improve consumers' confidence that all pharmacists registered by the Board who compound medicines are held to appropriate standards. The guidance advises pharmacist to compound medicines only when a commercially available medicine does not exist, is unsuitable or unavailable in the timeframe that the medicine is required by the patient. Most patients' needs can be met by supplying a medicine on the Australian Register of Therapeutic Goods (ARTG). For human use, medicines on the ARTG have been evaluated for quality, safety and, where appropriate, efficacy and/or performance. Other pathways to access commercially available medicines not on the ARTG may also be appropriate. For veterinary medicines, registered products are included on the Australian Pesticides and Veterinary Medicines Authority's Public Chemicals Registration Information System (APVMA PubCRIS) database.

D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

Board assessment

The Board has closely considered the potential costs associated with the proposal and concludes that the likely costs are minimal as the Board is not proposing significant changes.

If approved, the proposed compounding guidelines will provide practitioners with clear, consistent guidance when compounding medicines. The benefits of the revised guidelines will outweigh any minimal costs related to health practitioners and other stakeholders needing to become familiar with revised guidance.

E. Whether the proposal's requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants

Board assessment

The Board is committed to a plain English approach that will help pharmacists and the public understand the standards expected by the Board, their professional peers and the community. The revised compounding guidelines have been updated considerably to ensure that plain English is used and to enable understanding of the Board's requirements.

F. Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time

Board assessment

The Board has procedures in place to suppot a review of the compounding guidelines at least every five years.

The Board may choose to review the compounding guidelines earlier in response to any issues that arise or new evidence that emerges to ensure their continued relevance and workability.

Attachment F

National Boards' Patient and Consumer Health and Safety Impact Statement

May 2023

Statement purpose

The National Boards' Patient and Consumer Health and Safety Impact Statement (Statement)[1] explains the potential impacts of a proposed registration standard, code or guideline on the health and safety of the public, vulnerable members of the community and Aboriginal and Torres Strait Islander Peoples.

The four key components considered in the Statement are:

1. The potential impact of the proposed revisions to the guidelines on the health and safety of patients and consumers, particularly vulnerable members of the community, including approaches to mitigate any potential negative or unintended effects
2. The potential impact of the proposed revisions to the guidelines on the health and safety of Aboriginal and Torres Strait Islander Peoples, including approaches to mitigate any potential negative or unintended effects
3. Engagement with patients and consumers particularly vulnerable members of the community about the proposal
4. Engagement with Aboriginal and Torres Strait Islander Peoples about the proposal.

The National Boards' Health and Safety Impact Statement aligns with the National Registration and Accreditation Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025 , National Scheme engagement strategy 2020-2025 , National Scheme Strategy 2020-25 and reflects key aspects of the revised consultation process in the Ahpra Procedures for the development of registration standards, codes and guidelines and accreditation standards.

[1] This statement has been developed by Ahpra and the National Boards in accordance with section 25(c) and 35(c) of the *Health Practitioner Regulation National Law* as in force in each state and territory (the National Law). Section 25(c) requires AHPRA to establish procedures for ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice. Section 35(c) assigns the National Boards functions to develop or approve standards, codes and guidelines for the health profession including the development of registration standards for approval by the COAG Health Council and that provide guidance to health practitioners registered in the profession. Section 40 of the National Law requires National Boards to ensure that there is wide-ranging consultation during the development of a registration standard, code, or guideline.

Below is our initial assessment of the potential impact of the proposed revised *Guidelines on compounding of medicines* on the health and safety of patients and consumers, particularly vulnerable members of the community, and Aboriginal and Torres Strait Islander Peoples.

1. How will this proposal impact on patient and consumer health and safety, particularly vulnerable members of the community? Will the impact be different for vulnerable members compared to the general public?

In seeking to put forward the best option for consultation, the Pharmacy Board of Australia (the Board) has carefully considered the impacts the proposed revised guidelines could have on patient and consumer health and safety, particularly vulnerable members of the community. The proposed revisions are informed by stakeholders and subject matter experts as well as local and international standards. Our engagement through consultation will help us to better understand possible outcomes and meet our responsibilities to protect patient safety and health care quality.

2. How will consultation engage with patients and consumers, particularly vulnerable members of the community?

Preliminary confidential consultation was undertaken to test the consultation material with key stakeholders to ensure clarity and to make any amendments before proceeding to wide-ranging public consultation. It also provided an opportunity for feedback on the structure and/or wording of the draft revised guidelines.

The Board is now undertaking wide-ranging public consultation, during which it will engage with patient and consumer organisations, peak bodies and other relevant organisations to gain input and views from vulnerable members of the community. To assist with engagement with consumers, the Board has prepared a consumer fact sheet as part of the consultation package.

3. What might be the unintended impacts for patients and consumers particularly vulnerable members of the community? How will these be addressed?

The Board has carefully considered potential unintended impacts of the revised guidelines. Consulting with relevant organisations and vulnerable members of the community will help us to identify other possible impacts.

The Board will fully consider and, if needed, take action to address any potential negative impacts for patients and consumers that may be raised during consultation particularly for vulnerable members of the community.

4. How will this proposal impact on Aboriginal and Torres Strait Islander Peoples? How will the impact be different for Aboriginal and Torres Strait Islander Peoples compared to non-Aboriginal and Torres Strait Islander Peoples?

The Board's proposed option has carefully considered the potential impact of the revised guidelines on Aboriginal and Torres Strait Islander Peoples and how this may differ to the impact on non-Aboriginal and Torres Strait Islander Peoples. Our engagement through consultation will help us to identify any other potential impacts and meet our responsibilities to protect safety and health care quality for Aboriginal and Torres Strait Islander Peoples.

5. How will consultation about this proposal engage with Aboriginal and Torres Strait Islander Peoples?

The Board is committed to the National Scheme's Aboriginal and Torres Strait Islander Cultural Health and Safety Strategy 2020-2025, which focuses on achieving patient safety for Aboriginal and Torres Islander Peoples as the norm, and the inextricably linked elements of clinical and **cultural safety**.

As part of our consultation process, we will engage with Aboriginal and Torres Strait Islander organisations and stakeholders.

6. What might be the unintended impacts for Aboriginal and Torres Strait Islander Peoples? How will these be addressed?

The Board has carefully considered potential unintended impacts for Aboriginal and Torres Strait Islander Peoples. Engagement with relevant organisations and Aboriginal and Torres Strait Islander Peoples will help us to identify other potential impacts. We will consider and take action to address any potential negative impacts for Aboriginal and Torres Strait Islander Peoples that may be raised during consultation.

7. How will the impact of this proposal be actively monitored and evaluated?

Part of the Board's work in keeping the public safe is ensuring that all Board standards, codes and guidelines are regularly reviewed.

The Board will regularly review the revised guidelines to check they are working as intended.

Guidelines on compounding of medicines review - response template

The Pharmacy Board of Australia is inviting feedback on its draft revised *Guidelines for compounding of medicines* (the draft revised guidelines). Optional questions have been provided below and you may wish to address some or all of these in your response.

Published submissions will include the names (if provided) of the individuals and/or organisations making the submission unless confidentiality is requested.

Do you want your responses to be published after public consultation?

☐ Yes, I want my responses to be published after public consultation

☐ No, I do not want my responses to be published after public consultation

Submissions for website publication should be sent in Word format or equivalent.[1]

Name: _____

Organisation: _____

Contact email: _____

Please note this response template contains the same questions as the online survey. Please choose only ONE method of responding to avoid duplicating your submission.

[1] We aim to publish documents in accessible formats (such as word files) to meet international website accessibility guidelines. Therefore, while you are welcome to supply a PDF file of your feedback, we ask that you also provide a text or word file. More information about this is available at https://www.ahpra.gov.au/About-Ahpra/Accessibility.aspx

	Question	Your feedback (include guideline number/section)
1	The revised compounding guidelines include additional content on medicine supply pathways to consider before deciding if it is appropriate to compound a medicine (Guideline 1 When to compound medicines). **Is the new content on medicine supply pathways clear and helpful? Why or why not?**	
2	The compounding guidelines advise that a copy of the formula for their compounded medicine (listing all active ingredients and their strengths, and all inactive ingredients) must be provided to the patient when requested (Guideline 13 Supporting informed patient choice). Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. **Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?**	
3	The revised compounding guidelines include content that is specific to medicines compounded for animal patients. **Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?**	
4	**Is there any content that needs to be changed, added or deleted in the revised guidelines? If so, please provide your suggestions and reasons.**	
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	
6	**Please provide any other feedback about the revised guidelines.**	

	Question	Your feedback (include guideline number/section)
7	The Board proposes to retire the *Professional practice profile* for pharmacists undertaking complex compounding, as a professional practice profile should be practitioner specific, describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Individuals should develop their own practice profile by selecting the relevant competencies from the competency standards and customising them for use in their own practice setting. **Do you agree with the Board's proposal to retire the currently published *Professional practice profile* for pharmacists undertaking complex compounding? Why or why not?**	
8	The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation. **Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?**	