



## Public consultation

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28 April 2014

### You are invited to provide feedback on this public consultation

Review of the draft *Guidelines on compounding of medicines*

**Please provide feedback in a word document (or equivalent)<sup>1</sup> to [pharmacyconsultation@ahpra.gov.au](mailto:pharmacyconsultation@ahpra.gov.au) by close of business on Monday 30 June 2014.**

#### Public consultation

The Pharmacy Board of Australia (the Board) is releasing the attached consultation paper on its draft *Guidelines on compounding of medicines*.

You are invited to provide your comments on the consultation paper, including the questions in the paper, by close of business on Monday 30 June 2014. A template document for your response has been provided for your convenience. The feedback from this consultation will be considered by the Board in its further development and finalisation of these guidelines.

#### How your submission will be treated

Submissions will generally be published unless you request otherwise. The National Boards publish submissions on their websites to encourage discussion and inform the community and stakeholders. However, the National Boards retain the right not to publish submissions at their discretion, and will not place on their website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the consultation.

Before publication, the National Boards will remove personally-identifying information from submissions, including contact details. The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the National Boards.

The National Boards also 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 These submissions will not be published on the website or elsewhere.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* (Cwlth), which has provisions designed to protect personal information and information given in confidence.

Please let the Board know if you do not want your submission published, or want all or part of it treated as confidential.

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<sup>1</sup> You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you do supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at [www.ahpra.gov.au/About-AHPRA/Accessibility.aspx](http://www.ahpra.gov.au/About-AHPRA/Accessibility.aspx).

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## Overview of consultation

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28 April 2014

### Review of the draft *Guidelines on compounding of medicines*

#### Summary

1. The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), empowers the National Boards to develop and approve codes and guidelines to provide guidance to the profession.
2. The Board entered the National Registration and Accreditation Scheme (the National Scheme) on 1 July 2010 and developed guidelines and codes for its commencement. These guidelines and codes were scheduled for review at least every three years.
3. The National Law requires the Boards to ensure there is wide-ranging consultation on the content of any proposed code or guideline.
4. This consultation paper seeks feedback on the draft Guidelines on compounding of medicines which are to replace Guideline 5 Extemporaneous dispensing (compounding) of the Board's current Guidelines for dispensing of medicines which are also under review. The Guidelines on compounding of medicines will provide guidance to pharmacists who extemporaneously prepare medicines. The Board will also be developing Frequently Asked Questions (FAQs) to supplement the guidelines, which will be published at the same time as the guidelines.
5. The Board is inviting general comments on the draft guidelines. There are also specific questions about the guidelines in this consultation paper which you may wish to address in your response.
6. The Board will consider the consultation feedback in its further development and finalisation of the guidelines for publication.

**Please provide feedback in a word document (or equivalent) to [pharmacyconsultation@ahpra.gov.au](mailto:pharmacyconsultation@ahpra.gov.au) by close of business on Monday 30 June 2014.**

#### Background

7. The Board has developed draft Guidelines on compounding of medicines from the current Guideline 5 Extemporaneous dispensing (compounding) of the Board's Guidelines for dispensing of medicines. Throughout this consultation paper, the draft Guidelines on compounding of medicines will be referred to as the 'draft guidelines'.
8. It is proposed that Guideline 5 Extemporaneous dispensing (compounding) will be removed from the set of Guidelines for dispensing of medicines, and published as separate guidelines. A summary of the key differences between the draft guidelines and Guideline 5 Extemporaneous dispensing (compounding) is provided on page 19 of this consultation paper, to allow for easy comparison of these guidelines. The Board will also be conducting public consultation on draft revised Guidelines for dispensing of medicines separate to this consultation, later in 2014.
9. The draft guidelines refer to sources of compounding information that pharmacists undertaking compounding are expected to access to ensure their practice is acceptable. They also address issues of concern by providing additional guidance and, where appropriate, providing clarification, interpretation and guidance to benefit pharmacists in their practice.
10. For example, the draft guidelines provide further clarification and guidance on the risks associated with compounding, and circumstances where it may be inappropriate to compound a product.
11. The draft guidelines provide guidance on both 'simple compounding' and 'complex compounding', as defined in the Australian Pharmaceutical Formulary and Handbook (22nd Edition). Guidance is provided on how a pharmacist can be adequately prepared to expand their scope of practice to include:

- complex compounding which may include sterile manufacture (including the reconstitution of sterile products), and
  - the compounding of a broader range of products such as veterinary products which is likely to require additional knowledge and experience.
12. The draft guidelines outline that pharmacists undertaking complex compounding must be competent to do this, and that suitable training should be undertaken and adequate experience obtained. Guidance on suggested references for pharmacists undertaking compounding is included, acknowledging that references which meet the needs of pharmacists will vary depending on the scope of practice and the range of products compounded.
13. The draft guidelines acknowledge the relevance in practice of:
- state, territory and Commonwealth legislation
  - codes and guidelines published by jurisdictional Pharmacy Registering Authorities
  - the professional practice standards on compounding, and
  - the section on extemporaneous dispensing in the current edition of the *Australian pharmaceutical formulary and handbook*.
14. Where appropriate, the draft guidelines refer pharmacists to these sources of information which the Board, the profession and the public would expect compounding pharmacists to comply with. The Board deliberately avoided providing summaries of aspects of the practice standards in the draft guidelines as it holds the view that compounding pharmacists are expected to comply with all aspects of the practice standards when undertaking any type of compounding.
15. Failure to comply with the existing practice standards and guidelines published by the Board may result in a number of outcomes, including disciplinary action by the Board. As outlined in section 41 of the National Law, a guideline issued by the Board may be admissible in proceedings under the National Law against a pharmacist as evidence of what constitutes appropriate professional conduct or practice.

#### **Information sheet – Information on compounding for pharmacists**

16. The Board has identified information on the regulatory environment for compounding by pharmacists that may be helpful to practitioners, and proposes to publish this on its website as a separate information sheet. This is not part of the draft revised guidelines or the current consultation, as it relates to the requirements of other entities such as the Therapeutic Goods Administration (TAG) and the Australian Pesticide and Veterinary Medicines Authority (APVMA). The information included in the section 'Background on the regulation of compounding by pharmacists' in this consultation paper will form the basis of the separate information sheet for pharmacists and will be accessible from the Board's website alongside the published final version of the guidelines.

#### **Practice profile for pharmacists undertaking complex compounding**

17. On behalf of the profession, the Board engaged a consultant to develop a draft Professional practice profile for pharmacists undertaking complex compounding (practice profile). From the National Competency Standards Framework for Pharmacists in Australia, 2010, the competencies relevant to compounding have been customised to articulate the competencies required to provide complex compounding services. The practice profile is referenced in the draft guidelines.
18. The purpose of the practice profile is to assist pharmacists to understand the performance expected when undertaking complex compounding and consequently to identify any suitable activities to be undertaken to provide 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.
19. To deliver courses on complex compounding, training program providers may use the practice profile and the professional practice standards on compounding, to develop programs for delivery to pharmacists seeking to extend their scope of practice to include complex compounding.
20. The practice profile referenced in the draft guidelines will be published separately on the Board's website once finalised. A separate consultation on the draft practice profile is currently taking place.

You are invited to provide specific feedback on the content and structure of the practice profile by making a separate submission to the Consultation on the draft Professional practice profile for pharmacists undertaking complex compounding.

### You are invited to provide feedback

The Board is seeking feedback on the draft *Guidelines on compounding of medicines* including the following questions:

- Do the draft guidelines clearly differentiate between simple compounding and complex compounding?
- Do the draft guidelines clearly outline which requirements apply to pharmacists who undertake either or both types of compounding (simple and/or complex compounding), and which requirements apply only to pharmacists who undertake complex compounding?
- Is the content of the draft guidelines helpful?
- Is there any content that needs to be changed, added or deleted in the draft guidelines?
- Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board to support the guidelines?
- Is the purpose of the practice profile clearly explained in the draft guidelines?
- Do you have any other comments on the draft guidelines?

### Estimated impacts of the draft guidelines

21. The changes proposed in the draft guidelines are minimal, although more significant changes may be proposed through consultation. There is little impact anticipated on practitioners, business and other stakeholders arising from the changes proposed.
22. The draft guidelines articulate that pharmacists who are undertaking, or intend to undertake, simple or complex compounding are expected to comply with existing practice standards and the section on extemporaneous dispensing in the current edition of the Australian pharmaceutical formulary and handbook (APF). The Board's current Guidelines on practice specific issues (Guideline 1 – References) outlines that all pharmacists are required to access a current edition of the APF whilst practising. The content of the APF is subject to change with the publication of updated editions. The Board has a representative on the APF23 Stakeholder Consultation Group which enables the Board to provide comments to the APF Editorial Board on draft material proposed in the development of the next edition of the APF. It also provides an opportunity to identify issues which may require modification to the Board's guidelines on compounding to achieve appropriate alignment of compounding information and guidance.
23. Pharmacists undertaking complex compounding are also expected to access training programs which address the competencies outlined in the practice profile as part of meeting the requirements of the Board's Continuing professional development registration standard, to competently and safely provide compounding services to the public.
24. The proposed changes are intended to provide assurance to the public and the profession that pharmacists who undertake complex compounding are competent to do so, and to provide greater clarity and additional guidance for pharmacists on compounding. The draft guidelines will also require pharmacists to become familiar with a new set of guidelines.

### Relevant sections of the National Law

25. Section 35 of the National Law allows the National Boards to develop or approve standards, codes and guidelines for the health profession, including the development and approval of codes and guidelines that provide guidance to health practitioners registered in the profession. Section 39 explicitly states that a National Board may develop and approve codes and guideline to provide guidance to the health practitioners it registers; and about other matters relevant to the exercise of its functions.

# Background on the regulation of compounding by pharmacists<sup>2</sup>

## Therapeutic goods legislation

The [Therapeutic Goods Act 1989 \(Cwlth\)](#)<sup>3</sup> requires:

- a. therapeutic goods (which includes medicines) to be entered on the [Australian Register of Therapeutic Goods \(ARTG\)](#)<sup>4</sup> before they can be supplied in Australia, unless exempt, and
- b. manufacturing of medicines to be in compliance with the [Australian Code of good manufacturing practice for medicinal products](#)<sup>5</sup> and to occur in premises licensed by the Therapeutic Goods Administration (TGA), unless exempt.

The [Therapeutic Goods Regulations 1990](#)<sup>6</sup> provide the following exemptions relevant to pharmacists in relation to the extemporaneous preparation (compounding) of medicines:

- a. Australian Register of Therapeutic Goods:

Compounded medicines 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.

- b. Manufacturing of medicines:

A licence from the TGA is not required when:

- i. practising:
  - in a pharmacy which is open to the public, or
  - in a Friendly Society dispensary, 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 meeting the quality standards set out in the Therapeutic Goods Act 1989 (Cwlth).

This information is subject to possible change with amendments to TGA legislation. Refer to [www.tga.gov.au](http://www.tga.gov.au) for further information.

## Compounding veterinary products

The *Agricultural and veterinary chemicals code* (AgVet Code) specifies that to compound a medicine for animal use, a pharmacist must have received instructions from a veterinary surgeon.

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<sup>2</sup> The information included in this section, *Background on the regulation of compounding by pharmacists*, will be developed into an information sheet for pharmacists and published on the Board's website.

<sup>3</sup> Available at [www.comlaw.gov.au/Series/C2004A03952](http://www.comlaw.gov.au/Series/C2004A03952)

<sup>4</sup> Available at [www.tga.gov.au/industry/artg.htm](http://www.tga.gov.au/industry/artg.htm)

<sup>5</sup> Available at [www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm](http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm)

<sup>6</sup> Available at [www.comlaw.gov.au/Series/F1996B00406](http://www.comlaw.gov.au/Series/F1996B00406)

(Note: While the Agvet Code does not require the instruction 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. Refer to [www.apvma.gov.au](http://www.apvma.gov.au) for further information).

This contrasts with the Therapeutic Goods Act 1989 (Cwlth) which permits pharmacists to compound non-prescription ingredients for human use for individual patients without an instruction from a health practitioner.

### **Premises at which medicines may be compounded and supplied to patients**

The Therapeutic Goods Regulations 1990 outlines the circumstances under which a manufacturing site does not require a licence from TGA.

Pharmacists may only supply medicines which have been prepared extemporaneously at the pharmacy or private hospital at which they are practising.

Similarly, pharmacists cannot prepare medicines extemporaneously at a pharmacy or private hospital for supply by wholesale unless their premises are a TGA licensed manufacturer.

If employed in a public hospital or public institution, pharmacists may manufacture therapeutic goods for supply in a public hospital or public institution in the same state or territory.

Pharmacists may be subject to action by the TGA if found to be supplying compounded medicines outside of these circumstances.

(Refer to [www.tga.gov.au](http://www.tga.gov.au) for further information).

### **Obligation to meet relevant legislation, guidelines published by the Pharmacy Board of Australia and professional practice standards**

When compounding, in addition to the legislation outlined above, pharmacists have obligations under other relevant state, territory and Commonwealth legislation regarding issues such as advertising and workplace/premises requirements. They are also expected to comply with relevant professional practice standards and guidance published by the Board in its guidelines. The Board has published/is in the process of publishing its *Guidelines on compounding of medicines*. The guidelines specify the relevant practice standards which pharmacists must comply with when compounding medicines.

Regardless of the type of premises where a pharmacist practices, for example public hospital, public institution or privately operated pharmacy, there is no difference in the quality of compounding service expected by the Board.

### **Audit**

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 themselves.

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

# Draft *Guidelines on compounding of medicines*

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**Effective from:** <<date>>

**Review date:** <<date>>

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These guidelines have been developed by the Pharmacy Board of Australia (the Board) under s. 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 those registered in the profession 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 all pharmacists registered in the following categories:

- a) general
- b) provisional
- c) limited.

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

## Introduction

The intent of these guidelines is to provide guidance to pharmacists in relation to the compounding of medicines. They should be used in combination with the Board's *Guidelines for dispensing of medicines* which also apply to the dispensing and supply of compounded medicines.

These guidelines provide guidance and clarification on specific issues regarding compounding of medicines. They aim to minimise the associated risks for patients, pharmacists and other pharmacy staff, and improve patient outcomes and patient safety.

These guidelines are not the sole or primary source of information for pharmacists regarding compounding. They do not aim to restate or summarise already published and widely accepted information such as the compounding information contained in the *Australian pharmaceutical formulary and handbook*, the practice standards on compounding published by the profession, and the requirements outlined in relevant legislation.

### Relevant legislation and practice standards

Pharmacists are expected to be aware of and comply with the practice standards on compounding as listed below, including any other standards or guidelines referred to in those standards. Additionally, pharmacists must meet their obligations outlined in relevant legislation, as they relate to the preparation, storage, dispensing and supply of compounded medicines. The Board's *Background on the regulation of compounding by pharmacists* information sheet contains information on the requirements of other authorities under their specific legislation, which relate to compounding.

These guidelines must be read in conjunction with:

- state, territory and Commonwealth legislation relevant to the practice of pharmacy
- codes and guidelines published by jurisdictional pharmacy registering authorities about pharmacy premises
- the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*
- the following practice standards:
  - The Pharmaceutical Society of Australia Professional practice standards - *Standard 10: Compounding (also known as Extemporaneous Dispensing)*
  - The Pharmaceutical Society of Australia Professional practice standards - *Standard 11: Compounding sterile preparations*
  - The Society of Hospital Pharmacists of Australia *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*
  - Occupational, health and safety standards, and
  - Australian standards for cleanrooms.

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

- Pharmaceutical Society of Australia (PSA) ([www.psa.org.au](http://www.psa.org.au))
- The Society of Hospital Pharmacists of Australia (The SHPA) ([www.shpa.org.au](http://www.shpa.org.au))

*Note: As part of the agreement by the Council of Australian Governments to provide for the National Law, ownership of pharmacies, regulation of premises, inspections and related matters do not form part of the National Law, and each jurisdiction has/will have separate legislation and guidelines for these purposes.*

### What happens if I do not comply with these guidelines?

Pharmacists must comply with all legislation relevant to the practice of pharmacy in the jurisdiction where the practice occurs. Failure to practise in accordance with these requirements may give rise to action by one or more responsible authorities. These matters may then be referred to the Board for appropriate action under the National Law.

Non-compliance with these guidelines and the practice standards relevant to compounding may also be notified directly to the Board for appropriate action under the National Law. Non-compliance may be reported by an individual lodging a notification form, or through other means such as notification of outcomes of audits carried out by a pharmacy registering authority.

Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the Law as evidence of what constitutes appropriate professional conduct or practice for pharmacy. When considering notifications (complaints) against pharmacists, the Board will give consideration to whether a breach of these guidelines has taken place. The Board will also have regard to the legislation and practice standards relevant to pharmacy practice.

Further information for pharmacists regarding the possible outcomes of notifications is available on the website of the Australian Health Practitioner Regulation Agency (AHPRA) ([www.ahpra.gov.au](http://www.ahpra.gov.au)).

## Guidelines

**This guidance applies to both simple and complex compounding, unless otherwise stated.**

Pharmacists are permitted to compound (extemporaneously prepare) medicines for patients in accordance with the provisions of the therapeutic goods legislation. This may be in response to:

- a prescription, or
- a request for a compounded non-prescription medicine such as unscheduled, Schedule 2 or Schedule 3 medicines (where permitted by legislation).

Pharmacists are also permitted to compound veterinary pharmaceutical products provided that instructions have been received from a veterinary practitioner as outlined in the *Agricultural and veterinary chemicals code (AgVet Code)*.

A compounded medicine should be prepared only:

- in circumstances where an appropriate commercial product is unavailable or unsuitable, and
- if the pharmacist and other staff involved have completed education and training in the types of compounding they undertake, and have demonstrated competence in the relevant compounding techniques.

A commercial product may be considered unsuitable for a particular patient if an allergy to an excipient in the commercial product was experienced.

In preparing a compounded medicine, a corresponding formulation in a reputable reference should be used by the pharmacist when available.

(Note: For further information, refer to:

- <http://www.tga.gov.au/industry/artg.htm>
- [www.apvma.gov.au](http://www.apvma.gov.au)
- Pharmacy Board of Australia *Background on the regulation of compounding by pharmacists* published at [www.pharmacyboard.gov.au/Codes-Guidelines.aspx](http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx)).

### 1 Competence to undertake 'simple compounding'

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

Simple compounding may routinely involve compounding products:

- from formulations published in reputable references such as the *Australian pharmaceutical formulary and handbook*, excluding the preparation of sterile products from these formulations which is considered complex compounding, or
- using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available.

Simple compounding requires the use of current clinical and pharmaceutical knowledge and appropriate compounding techniques. It must be carried out in accordance with the relevant professional practice standards outlined in these guidelines and all legislation relevant to the practice of pharmacy.

## 2 Competence to undertake 'complex compounding'

Subsequent to entering the profession, some pharmacists may extend their scope of practice to compound medicines of a more complex nature ('complex compounding') which requires or involves specific competencies, equipment, processes and/or facilities to manage the higher risks associated with the preparation and dispensing of these medicines. Examples of complex compounded products are sterile preparations, preparations containing ingredients posing an occupational health and safety hazard such as cytotoxics or hormones, monoclonal antibodies, micro-dose single unit dosage forms containing less than 25mg of active ingredient, tablets, capsules, troches and modified-release preparations.

### *Professional practice profile for pharmacists undertaking complex compounding*

On behalf of the profession, the Board has developed the *Professional practice profile for pharmacists undertaking complex compounding* (practice profile). The practice profile articulates the competencies required for specific roles, services or positions relevant to complex compounding. Pharmacists should review the practice profile to understand the performance expected when undertaking complex compounding.

To deliver courses on complex compounding, training program providers may use the practice profile and the professional practice standards on compounding, to develop programs for delivery to pharmacists seeking to extend their scope of practice to include complex compounding.

### *Demonstrating competence to undertake complex compounding*

The Board's *Registration standard: Continuing professional development* (the CPD registration standard) requires pharmacists to undertake CPD activities that are relevant to their scope of practice. When pharmacists extend their scope of practice to include complex compounding they must be able to demonstrate that they have met the requirements of the CPD registration standard by maintaining evidence of the CPD activities they have undertaken to achieve competence to undertake complex compounding. The education/CPD activities and training undertaken must address the competencies outlined in the practice profile. Pharmacists should seek information from potential education/CPD providers to demonstrate how the available programs address these competencies.

Demonstrating competence to undertake complex compounding, to ensure safety of the public who access their services, themselves and the staff working under their supervision, involves:

- a. conducting a self assessment against the practice profile to identify the competencies relevant to the areas of complex compounding undertaken or to be undertaken
- 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 sufficient experience in premises that are adequately designed, equipped, maintained and approved by relevant authorities.

Engagement of an expert or mentor to assist with this process is encouraged.

The maintenance of competence of pharmacists and other staff who prepare compounded medicines which require specific skills (e.g. sterile preparations), should be demonstrated by regular workplace validation of preparation techniques (also refer to Guideline 5 *Supervision of appropriately trained staff* and the practice standards on compounding).

### *Veterinary products*

Pharmacists who intend to compound simple and complex veterinary products are expected to have undertaken education in the compounding of products for the treatment of animals and to have undertaken sufficient training.

## 3 Formulation considerations

When compounding medicines, pharmacists must ensure that there is good clinical and pharmaceutical evidence to support the quality, stability (including appropriate expiry periods), safety, efficacy and

rationality of any extemporaneous formulation. The dispensing and supply of a compounded medicine must be consistent with the safety of the patient (refer to Guideline 1 *Dispensing precaution – safety of prescriptions* of the Board's *Guidelines for dispensing of medicines*).

Evidence to support a decision to compound a medicine must be obtained from reputable references (refer to the reference texts for compounding pharmacists listed in these guidelines), international pharmacopoeial standards, or peer reviewed journals, and must not be based on testimonials and impressions.

#### *Formulations for which precedents do not exist*

A decision to prepare a formulation for which there is no precedent in a reputable reference must be supported by the pharmacist's sound judgment based on current clinical and pharmaceutical knowledge and risk assessment. The pharmacist must ensure that the patient has been made aware that the compounding is taking place under these circumstances.

Particular care should be exercised by pharmacists who are requested to compound medicines for which there are no precedents in the reputable references and for which there is inadequate published safety, efficacy, pharmacokinetic and clinical data on the intended formulation. Examples of such products could include (but are not limited to):

- preparations containing hormones
- substances not approved in Australia for therapeutic use
- preparations compounded for topical use that contain drugs for which only oral use is well established
- modified release medicine in the absence of good pharmacokinetic and clinical data on the precise formulation intended for use, and
- parenteral medicines containing combinations of ingredients where there is no compatibility data.

The compounding of such products must be justified. If deciding to compound such products, a pharmacist should document:

- evidence of appropriateness of the intended formulation which is accessible for all future compounding of this formulation, which includes:
  - evidence of the efficacy, pharmacokinetic and clinical data, and the basis for the assigned expiry date of the intended formulation
  - the process to maintain the safety of the pharmacy staff where the compounding is taking place
- any other steps in relation to ensuring that the dispensing and supply of the compounded medicine is consistent with the safety of the individual patient.

In the absence of such documented evidence, pharmacists must not compound such products.

#### *Compounding of parenteral medicines in advance*

Preparation of compounded parenteral medicines in advance may potentiate the risks associated with compounding, including:

- enhanced chemical instability of the compounded product
- increased likelihood of microbial contamination of the compounded product, and
- increased likelihood of dose administration errors associated with the compounded product.

Only medicines for parenteral administration with a shelf life of up to 24 hours should be compounded by a pharmacist for use by a specific patient.

#### *Manipulation of products in accordance with manufacturer's instructions*

Pharmacists may be required to manipulate a commercially available product in accordance with the manufacturer's instructions, in order to produce a product in a 'ready-to-administer' form. This type of activity is considered compounding, and the guidance contained in these guidelines applies.

#### *Modification of commercially available products*

A decision to alter a commercially manufactured medicine not in accordance with the manufacturer's instructions must only be made:

- where details including the stability and formulation of the modified product are available, and
- following communication with the prescriber if prescribed, and the patient or agent.

Patient safety should not be compromised as a result of the modification, particularly in the interests of cost.

The modification must be recorded in the patient medication record and endorsed on the prescription and duplicate (if prescribed). Unless part of the licence indication, manufacturers of commercially manufactured medicines are unlikely to support modifications to these medicines, and are not responsible for the quality, safety and/or efficacy of the resultant product.

#### *Risk assessment process for compounded products*

Pharmacists who compound products must have appropriate risk management processes in place to manage risks associated with the compounded product and the workplace (for maintenance of facilities, quality assurance of products including microbial testing, occupational health and safety adherence, professional indemnity insurance arrangements etc). The risk assessment and management processes must align with practice standards and the standards set by relevant regulatory bodies at the federal and state and territory level.

Pharmacists are referred to the 'Risk assessment process for the preparation of extemporaneous preparations' outlined in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*. In the case of complex compounding, pharmacists are advised to document this process.

A pharmacist may be required to compound a particular product for more than one patient, for example in circumstances where the pharmacist is located near a prescriber who regularly prescribes a particular product. Before compounding, the pharmacist must consider the risks associated with batch preparation, such as a compounding error or contamination having the potential to affect a larger number of patients. For such reasons, the Board discourages batch preparation.

#### **4 Supervision of appropriately trained staff**

To assist with the compounding of medicines, pharmacists may engage suitably trained and experienced dispensary assistants or dispensary technicians working under their direct supervision in accordance with the guidance in *Guideline 11 Dispensary assistants/dispensary technicians and hospital pharmacy technicians* of the Board's *Guidelines for dispensing of medicines*.

Where a dispensary assistant or dispensary technician assists with the physical compounding of a medicine, it is the pharmacist's responsibility to:

- conduct a risk assessment for the product being compounded, and ensure that all risks are appropriately managed
- ensure all weighing and measuring is conducted appropriately
- ensure all packaging and labelling of the compounded product is appropriate
- ensure that the product has been compounded in accordance with pharmacopoeial formulations when available, and in a manner which ensures quality and efficacy of the product
- ensure that the compounding procedure has been documented appropriately
- approve the supply of the medicine to the consumer, whether a prescription medicine or over the counter medicine, and
- counsel the patient and ensure that the patient is provided relevant information about the compounded product.

#### **5 Facilities, working environments and equipment**

Pharmacists and persons responsible for the operation of premises including proprietors, must ensure that all compounding takes place in premises that are adequately designed and equipped. Where required under relevant state and territory legislation, premises must be accredited or approved and/or registered by the relevant jurisdictional authority, and operate in accordance with any guidelines published by those authorities.

Facility, working environment and equipment specifications detailed in the relevant practice standards listed in these guidelines must be met for the type of compounding carried out. The guidance provided in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook* should also be followed.

Pharmacists should determine whether specific and separate facilities and equipment are required for compounding veterinary products or hazardous substances.

#### *Additional requirements relating to facilities, working environments and equipment applicable to complex compounding*

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

- the preparation of sterile and cytotoxic products to ensure products of an acceptable standard are produced, and
- the handling of hormones, cytotoxics and other hazardous material to ensure protection of pharmacy staff, patients and the public.

For additional guidance on facilities and equipment in relation to complex compounding, pharmacists should refer to the information published in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*.

### **6 Potential for contamination due to injury**

Routine precautions should be taken while compounding in order to reduce the risk of injury, for example needlestick injury while preparing sterile products, and to minimise the risk of contamination should injury occur. Any penetration to the compounder's skin must be appropriately managed in order to reduce the risk of contamination:

- of the product being compounded, which places the patient at risk, and
- of the local environment, which places other staff at risk.

Occupational health and safety requirements, and the professional practice standards outlined in these guidelines, must be complied with.

### **7 Raw materials**

For guidance on the standards for ingredients used for compounding, pharmacists should refer to the information published in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*. If there is a need to use a substance not approved for human use, the necessary evidence should be obtained to demonstrate that this substance complies with the requirements of pharmacopoeial standards.

### **8 Quality standards**

Pharmacists are referred to the quality assurance information published in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*.

Compounded medicines are not exempted from meeting the quality standards set out in the Therapeutic Goods Act 1989 (Cwlth). The required specifications for compounded medicines include relevant standards of the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopoeia, including relevant standards on microbiological quality of non-sterile pharmaceutical preparations. It is the pharmacist's responsibility to ensure that compounded medicines comply with the relevant standards.

### **9 Documentation**

Pharmacists should document the preparation of compounded products in accordance with state, territory and federal legislation, practice standards and the information published in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*.

Policies and procedures should be in place to:

- support the quality assurance of compounding activities within the pharmacy, and
- enable the recall of compounded products if required, for example to action a recall issued by the TGA.

Appropriate documentation is an essential component of each of these activities for every compounded product. Pharmacists are referred to the quality assurance information published in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*.

## **10 Adverse reactions**

Pharmacists should report adverse reactions to compounded medicines to the TGA. While it may be difficult to determine whether a particular medicine caused an adverse event in an individual case, all reports can help to build up a picture of the role of an ingredient or product in causing an adverse event. The reporting of adverse events associated with compounded products to the TGA is assisted by maintaining documentation. Information about adverse reporting, including how to lodge a report, is available at [www.tga.gov.au/safety/problem.htm#medicine](http://www.tga.gov.au/safety/problem.htm#medicine).

## **11 Packaging and labelling requirements**

Pharmacists should package and label compounded medicines in accordance with the requirements outlined in relevant state and territory legislation and guidelines, the guidance in Guideline 6 *Labelling of dispensed medicines* of the Board's *Guidelines for dispensing of medicines*, the practice standards and the information published in the section *Extemporaneous dispensing* in the current edition of the *Australian pharmaceutical formulary and handbook*.

## **12 Counselling**

Pharmacists should ensure that every patient or their agent are offered counselling on each occasion a compounded medicine is supplied (refer to Guideline 8 *Counselling patients about prescribed medications* of the Board's *Guidelines for dispensing of medicines*). This should be achieved by face-to-face contact whenever possible. When this is not possible, for example because of indirect supply of the compounded medicine to the patient, pharmacists should ensure they comply with Guideline 4 *Internet, mail-order dispensing and other indirect supply of medicines* of the *Guidelines for dispensing of medicines*.

## **13 Patients' rights to choose where to access all types of compounded medicines**

Patients have the right to choose where to access their medication.

Pharmacists must comply with the *Code of conduct for pharmacists*, which applies to the supply of commercially prepared and compounded medicines. The Code states:

*Providing good care includes:*

- e) *recognising and respecting the rights of patients or clients to make their own decisions.*

Pharmacists must not enter into arrangements for exclusive supply of prescriptions for compounded medications from a health practitioner/prescriber or other third party. With the patient's or client's consent, pharmacists may offer to retain prescriptions for subsequent dispensing.

## **14 Advertising**

If a pharmacist advertises a compounding service, this must be done in accordance with the current *Therapeutic Goods Advertising Code*, the *AgVet Code*, and the Board's *Guidelines for advertising of regulated health services*. Any products and/or services advertised must be limited to those for which an exemption is provided under therapeutic goods legislation and the *AgVet Code*.

Compounded medicines are subject to the advertising provision of the *Therapeutic Goods Act 1989* (Cwlth) and *Therapeutic Goods Regulations 1990*. Compounded medicines that are Schedule 3 (but not listed in Appendix H of the *Poisons Standard*), Schedule 4 and Schedule 8 cannot be advertised.

In the case of advertising the availability of a specific formulae or product, for a medicine that can be advertised (medicines that are unscheduled, Schedule 2 or Schedule 3 and included in Appendix H of the *Poisons Standard*), pharmacists are expected to provide evidence of its efficacy in the advertisement (refer to 3.3 *Substantiation of claims* in the Board's *Guidelines for advertising of regulated health services*).

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

## 15 Reference texts for compounding pharmacists

All pharmacists are required to have ready access to the *Australian pharmaceutical formulary & handbook* (refer to the *Guidelines on practice-specific issues – Guideline 1 (List of Reference texts for pharmacists)*). Additionally, compounding pharmacists must have available, appropriate reference texts 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. Examples may include the following:

- Martindale: The complete drug reference
- Trissel's Stability of compounded formulations - Trissel LA
- International journal of pharmaceutical compounding ([www.ijpc.com](http://www.ijpc.com))
- Australian don't rush to crush handbook – The Society of Hospital Pharmacists of Australia
- Handbook on injectable drugs - Trissel LA
- Pharmaceutical calculations - Howard C. Ansel and Mitchell J. Stoklosa
- The art, science and technology of pharmaceutical compounding – Loyd Allen
- Australian injectable drugs handbook
- Ansel's Pharmaceutical dosage forms and drug delivery systems – Loyd Allen
- Remington: The science and practice of pharmacy, edited by David B. Troy, Paul Beringer.

### Definitions

**Adverse event** (for the purpose of these guidelines, based on the definitions provided by the Therapeutic Goods Administration and the World Health Organization), 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.

**Batch** means a quantity of a product 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 product that is sterilized or freeze dried, sterilized or freeze dried in one cycle.

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

**Compounding** means the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for immediate use by a specific person in response to an identified need. For the purposes of these guidelines, the practice of compounding is classified as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding.

**Simple compounding** means the preparation and supply of a single 'unit of issue' of a therapeutic product intended for immediate use by a specific person in response to an identified need. It routinely involves the compounding of products from formulations published in reputable references such as the *Australian pharmaceutical formulary and handbook* (excluding the preparation of sterile products from these formulations, which is considered complex compounding), or using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available.

**Complex compounding** means the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for immediate use by a specific patient and that requires or involves specific competencies, equipment, processes or facilities. Examples include sterile preparations and preparations containing ingredients which pose an occupational health and safety hazard such as cytotoxics or hormones, monoclonal antibodies, micro-dose single unit dosage forms containing less than 25mg of active ingredient, tablets, capsules, troches and modified-release preparations.

**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 introductory paragraph under *Guidelines* in the Board's *Guidelines for dispensing of medicines*).

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

**Unit dosage formulation** is the individual dose to be delivered to a patient (e.g. a sterile preparation, tablet, capsule, pessary, suppository etc)

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

## References

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

- Guideline 4 *Internet, mail-order dispensing and other indirect supply of medicines*
- Guideline 6 *Labelling of dispensed medicines*
- Guideline 8 *Counselling patients about prescribed medicines*
- Guideline 11 *Dispensary assistant/dispensary technicians and hospital pharmacy technicians*

Pharmacy Board of Australia *Guidelines for proprietor pharmacists*

Pharmacy Board of Australia *Guidelines for advertising of regulated health services*

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 *Notifications in the National Scheme - A guide for practitioners*

## Review

These guidelines will be reviewed at least every five years.

Last reviewed: <<date>>

These guidelines replace the previously published guidelines from <<date>>

## Summary

### Summary of changes

The following table outlines the key differences between the draft revised *Guidelines on compounding of medicines* and the currently published *Guideline 5 Extemporaneous dispensing (compounding)* of the Board's *Guidelines for dispensing of medicines*, to allow for comparison of these guidelines.

Section in draft revised <i>Guidelines on compounding of medicines</i>	Change to currently published <i>Guideline 5 Extemporaneous dispensing (compounding)</i>	Rationale
<b>Title</b>	New title <i>Guidelines on compounding of medicines</i> to replace current title <i>Guideline 5 Extemporaneous dispensing (compounding)</i>	Acknowledges the common use of the term 'compounding' in practice.
<b>Preamble to the guidelines</b>	<p>Refers pharmacists to legislation and other relevant information relating to compounding, including specific practice standards and guidelines.</p> <p>Refers pharmacists to the Board's background information sheet on compounding, which outlines legislation permitting pharmacists to extemporaneously prepare medicines.</p> <p>Outlines consequences of non-compliance with requirements of external entities and Board guidance.</p>	<p>Provides clarification and guidance.</p> <p>The background information summarises the requirements of other entities such as the Therapeutic Goods Administration (TAG) and the Australian Pesticide and Veterinary Medicines Authority (APVMA). It is to be published separately to the guidelines and can be amended as required.</p>
<b>1 Competence to undertake 'simple compounding'</b>	Outlines that pharmacists entering the profession are deemed competent to undertake simple compounding, and the types of products this may involve.	Allows differentiation between simple compounding and 'complex compounding' which clarifies the obligations of pharmacists expanding their scope of practice to include complex compounding.
<b>2 Competence to undertake 'complex compounding'</b>	<p>Introduces and defines 'complex compounding', which expands the application of the guidelines beyond its current application to include for example sterile and cytotoxic preparation in any practice setting.</p> <p>Introduces the practice profile developed by the Board on behalf of the profession, including its purpose and application.</p> <p>Includes guidance to pharmacists</p>	<p>The draft guidelines link to the requirements of the CPD standard which requires pharmacists to undertake CPD relevant to their scope of practice.</p> <p>Provides clarification and guidance.</p>

Section in draft revised <i>Guidelines on compounding of medicines</i>	Change to currently published <i>Guideline 5 Extemporaneous dispensing (compounding)</i>	Rationale
	who may compound veterinary products, to gain education and training in this area.	
<b>3 Formulation considerations</b>	<p>Expands on existing content with additional examples of preparations requiring particular care. Outlines that pharmacists must not compound in absence of adequate evidence.</p> <p>Introduces guidance on the preparation of compounded medicines in advance. This includes a statement that only parenteral medicines with a shelf life of up to 24 hours should be compounded by a pharmacist for use by a specific patient. (Note: hospitals are exempted from this requirement. Further clarification to be provided in a Frequently Asked Question).</p> <p>Clarifies that manipulation of products in accordance with the manufacturer's instructions is compounding, and introduces guidance on recording if modifying commercially available products not in accordance with the manufacturer's instructions.</p> <p>Introduces guidance on risk assessment including documentation of risk assessment for complex compounding, and refers to the practice standards, the standards set by relevant regulatory bodies and the <i>Australian Pharmaceutical Formulary and Handbook</i>.</p> <p>Introduces guidance on batch preparation, including associated risks.</p>	<p>Provides clarification and guidance.</p>
<b>4 Supervision of appropriately trained staff</b>	<p>New section. Refers pharmacists to the <i>Dispensary assistants/ dispensary technicians and hospital pharmacy technicians</i> guideline in the Board's <i>Guidelines for dispensing of medicines</i>. Outlines which steps in the compounding process are the pharmacist's responsibility.</p>	<p>Provides additional guidance.</p>

Section in draft revised <i>Guidelines on compounding of medicines</i>	Change to currently published <i>Guideline 5 Extemporaneous dispensing (compounding)</i>	Rationale
<b>5 Facilities, working environments and equipment</b>	New section. Includes reference to 'approved and/or registered premises', and refers pharmacists to relevant practice standards and the <i>Australian Pharmaceutical Formulary and Handbook</i> .	Provides clarification and guidance.
<b>6 Potential for contamination due to injury</b>	New section. Includes guidance on the risk of injury including needlestick injury when compounding sterile products.	Provides additional guidance.
<b>7 Raw materials</b>	New section. Refers pharmacists to the <i>Australian Pharmaceutical Formulary and Handbook</i> . Addresses use of substances not approved for human use, and guidance on obtaining necessary evidence.	Provides additional guidance.
<b>8 Quality standards</b>	New section. Refers pharmacists to the <i>Australian Pharmaceutical Formulary and Handbook</i> , and reminds pharmacists that compounded medicines are not exempted from meeting the relevant quality standards.	Provides additional guidance.
<b>9 Documentation</b>	New section. Refers pharmacists to legislation, practice standards and the <i>Australian Pharmaceutical Formulary and Handbook</i> .  Introduces the requirement to have documented policies and procedures in place.	Provides additional guidance.
<b>10 Adverse reactions</b>	New section. Encourages pharmacists to report adverse reactions to compounded medicines to TGA, and to maintain adequate documentation to assist with this.	Provides additional guidance.
<b>11 Packaging and labelling requirements</b>	New section. Refers pharmacists to legislation, the Board's <i>Guidelines for dispensing of medicines</i> , and the <i>Australian Pharmaceutical Formulary and Handbook</i> .	Provides additional guidance.
<b>12 Counselling</b>	New section. Highlights the requirement for pharmacists to counsel patients on compounded medicines, as outlined in the Board's <i>Guidelines for dispensing of</i>	Provides additional guidance.

Section in draft revised <i>Guidelines on compounding of medicines</i>	Change to currently published <i>Guideline 5 Extemporaneous dispensing (compounding)</i>	Rationale
	<i>medicines.</i>	
<b>13 Patients' rights to choose where to access all types of compounded medicines</b>	New section. Refers pharmacists to the Board's <i>Code of conduct for registered health practitioners</i> and addresses exclusive supply arrangements.	Provides clarification and guidance.
<b>14 Advertising</b>	New section. Outlines when compounded medicines can be advertised. Refers pharmacists to legislation and guidelines relevant to the advertising of medicines.	Provides additional guidance.
<b>15 Reference texts for compounding pharmacists</b>	New section. Advises options for consideration by pharmacists based on their practice.	Provides clarification and guidance.
<b>Definitions</b>	New section. Defines terms used in the guidelines.	Provides clarification.
<b>References</b>	Refers pharmacists to several other documents which are relevant to compounding, including other Board guidelines.	Provides additional guidance.
<b>Review</b>	Addition of introductory text included in all revised Board guidelines.	For information and consistency.