Pharmacy Board
Ahpra

Guidelines on
compounding of medicines

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Contents

Who needs to use these guidelines? 3
How to read this document 3
Introduction 3
Relevant legislation, quality standards and practice standards 4
How may these guidelines be used? 6
Guidelines 7
1 When to compound medicines 7
Medicines for human use 7
Veterinary medicines 8
Further information 9
1.1 Considerations before compounding a medicine 9
1.2 Obligations when a prescribed or requested medicine cannot be compounded 11
2 Competence to undertake compounding 12
Veterinary medicines 12
3 Quality assurance 14
3.1 Sterile medicines 14
3.2 Self-assessment and audit 15
4 Facilities, equipment, working environments, materials and support staff 16
Ingredients 16
4.1 Risk assessment process for facilities and equipment 17
4.2 Ingredients 17
4.3 Supervision of support staff 17
5 Formulation considerations 19
5.1 Formulations for which precedents do not exist 19
5.2 Quantity to be supplied 20
5.3 Modification of commercial medicines 20
5.4 Risk assessment process for compounded medicines 21
5.5 Consistency of supply 21
6 Assigning expiry dates to compounded medicines 22
Expiry dates of compounded sterile injectable medicines 22
7 Batch preparation 23
8 Managing risks that may lead to injury 23
9 Documentation 24
10 Packaging and labelling requirements 25
11 Counselling and provision of information on compounded medicines 26
12 Supporting informed patient choice 27
13 Reporting of adverse events 28
14 Advertising 29
15 Reference texts and other sources of information relevant to compounding 30
Definitions 31
Interpretation 33
Board references 33
Additional information 34
Review 34

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)., The guidelines aim to inform registered pharmacists and the community about the Board's expectations of pharmacists in relation to compounding medicines. 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.

Education providers and employers may also bring these guidelines to the attention of their students and employees respectively.

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 about the issue, including references to relevant legislation, practice standards and essential references routinely used by pharmacists in practice such as the Australian Pharmaceutical Formulary and Handbook*
- *applicable explanatory information that is highlighted by the Board (not standards or requirements developed by the Board))*

Guidance

The Board's guidance for pharmacists about the issue.

- *(guidance statement)*

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 should always ensure that compounding practices are:

- compliant with relevant legislation
- compliant with relevant pharmacy practice standards and guidelines
- informed by 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
- aligned with the conduct expected of pharmacists as set out in the *Code of conduct* for pharmacists and codes of ethics for pharmacists
- compliant with all relevant Board guidelines for pharmacists

- 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
- manufacturing licence holder.

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

These guidelines are not a substitute for – and should 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 standards and requirements described above and named in these guidelines 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 and in the case of animals, the owner of the animal. 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.

Refer to *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 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 Act). Monographs in the *British Pharmacopoeia* (BP), *European Pharmacopoeia* (Ph Eur), and *United States Pharmacopoeia-National Formulary* (USP) are defined in the Act to be 'default standards' and apply to therapeutic goods (ingredients and formulated products) that are the subject of the relevant monographs. Where it is necessary to specify an Australian standard, a Therapeutic Goods Order (TGO) is approved under the Act and published on the TGA website. Refer to the TGA website for more information on ministerial and default standards.

State and territory legislation may also require compliance with specific standards and/or guides when compounding medicines.

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 regulatory bodies under their specific legislation, which relate to compounding.

Quality standards, practice standards and guidelines

Adhering to principles in quality standards/guides is crucial for safe compounding practice. Depending on a pharmacist's compounding practice, relevant standards may include, but are not limited to:

- 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) has 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*. This document may also be used as guidance to 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.

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

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

- the Code of conduct and the Board's guidelines for pharmacists (refer to *Guidelines* at the end of this document)
- standards, 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*
- relevant practice standards and guidelines published by:
  - the Pharmaceutical Society of Australia (PSA)
  - the Society of Hospital Pharmacists of Australia (SHPA)
- the *Agricultural and Veterinary Chemicals Code* (AgVet Code) when compounding for animal patients
- occupational, health and safety standards
- Australian standards for clean rooms (ISO 14644 is the adopted Aus/NZ standard).

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.(Except in Western Australia where state-specific requirements are on the WA Health website at ww2.health.wa.gov.au).
2. With limited exceptions (such as Schedule 5F of the National Law in force in New South Wales), 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 pharmacy 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.

5. The Board may amend and/or retire other Board guidelines referred to in this document and the guidelines in effect at the time when compounding medicines will apply.

How may these guidelines be used?

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 (refer to *Definitions*).

These guidelines are not legally binding rules or regulations. Their purpose is to assist the Board in its functions under the National Law relating to the protection of the public, by setting and maintaining standards of practice to guide pharmacists in relation to compounding medicine. Conduct that is not consistent with these guidelines and/or laws, practice standards or other guidelines relevant to compounding may 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 the pharmacist's conduct is consistent with these guidelines. The Board will also consider legislation, practice standards and guidelines relevant to pharmacy practice.

If a pharmacist’s professional conduct varies significantly from these guidelines, the pharmacist should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may have consequences for a pharmacist’s registration.

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

Guidelines

These guidelines apply to pharmacists when 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 (refer to *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.

For more examples of what is, and what is not, considered compounding, refer to the Compounding section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

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

Given this, the Board considers it necessary that compounding only occur after consideration of the matters and in the circumstances specified in the following guidelines. This is both to protect the public and promote public confidence in the safety of relevant health services.

Section 19A (s19A) of the *Therapeutic Goods Act 1989* allows medicines not currently registered in the ARTG to be imported into Australia and supplied:

- in place of a registered medicine that is unavailable or in short supply
- as a substitute for a medicine that was previously registered in Australia where it is in the interest of public health, 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 entered 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, as set out in the *Therapeutic Goods Regulations 1990* at the time of issuing these Guidelines, a pharmacist may (subject to compliance with all other relevant laws and guidelines):

- extemporaneously compound medicine (other than medicines that are used for gene therapy, that are medicinal cannabis products or that contain glucagon-like peptide-1 (GLP-1) receptor agonist analogues) ‘for a particular person for therapeutic application to that person’. In the Board's view, this means:
    - for a prescription only medicine the pharmacist has a prescription or order, and the patient has requested supply of the medicine before the pharmacist compounds the medicine
    - for a non-prescription medicine the patient has requested supply of the medicine before the pharmacist compounds the medicine.
- compound medicine in a hospital if the pharmacist is engaged in the manufacture of medicine at the hospital and 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.

Further details are set out in the relevant provisions in the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*.

Veterinary medicines

Registered veterinary chemical products for use in Australia are assessed for quality, efficacy and safety. 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. Medicines on the ARTG may also be suitable for animal use and may be prescribed by veterinarians. 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.

Further information

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

Consultation with the patient (or their agent) and their prescriber should 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 (refer to guideline *5.4 Risk assessment process for compounded medicines* for further information).

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

1.1.1 The availability of a commercial medicine

For the purposes of these guidelines:

- a ‘commercial medicine’ for human patients is an approved medicine which includes medicines on the ARTG and medicines approved for import and supply under s19A
- a ‘commercial medicine’ for animal patients is a registered veterinary chemical product included in the APVMA PubCRIS database or a medicine on the ARTG.

Medicines must 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), or
c. they are required for the purpose of research sanctioned by a recognised human or animal research ethics committee.

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

a. a commercial medicine, or combination of commercial medicines, 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 should not offer to compound the medicine, including if the medicine can be compounded at a lower price than the available commercial medicine.

Note: Unapproved medicines that are approved for use in Australia are available via other pathways such as the SAS or AP. The Board has not included medicines available via these pathways in the definition of a commercial medicine, however if readily available and appropriate for a patient, these may be a suitable alternative to a compounded medicine.

1.1.2 Competence to compound medicines

Medicines must only be compounded by competent individuals (refer to guideline 2 *Competence to undertake compounding* for more information).

1.1.3 The suitability of the compounding environment

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

1.1.4 Evidence to support compounding is available

Medicines should only be compounded if supported by 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) should be made aware that the medicine will be compounded and is not subject to the same processes as approved medicines and should provide informed consent to receiving a compounded medicine. This may not be possible in every circumstance (such as 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
- offer to discuss other suitable options that may address the patient's medication needs.

Also refer to the *Code of conduct* , 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 (*1.1 Providing good care (d))*
b. considering the balance of potential benefit and harm in all clinical management decisions (*1.2 Good care (d))*
c. providing treatment options based on the best available information and not influenced by financial gain or incentives (*1.2 Good care (f*))
d. consulting and taking advice from colleagues when appropriate (*1.2 Good care (k*))
e. practising within an evidence-based and patient-centred framework (*1.2 Good care (g)*)
f. facilitating the quality use of therapeutic products based on the best available evidence and the patient's needs (*1.2 Good care (o)*).

2 Competence to undertake compounding

Pharmacists entering the profession have had the appropriate education and training to compound medicines and are therefore expected to be 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*). Complex compounding requires and/or involves specific competencies, equipment, processes and facilities to manage the higher risks to the safety of patients 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 a pharmacist's scope of practice.

The *Code of conduct* describes the professional behaviour and conduct expected of pharmacists in relation to competence and continuing professional development (CPD). The Code of conduct states that good practice includes ensuring 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. This includes planning and satisfactorily completing the CPD activities that address the competencies relevant to complex compounding and maintaining evidence of the activities completed.

Ongoing competency should be maintained by ongoing practice and completion of CPD.

Veterinary medicines

Pharmacists who intend to compound simple and complex veterinary medicines should have completed CPD (education and training) in the compounding of medicines for the treatment of animals.

Guidance

To demonstrate ongoing competence to undertake complex compounding, pharmacists should:

a. conduct a self-assessment to identify the competencies relevant to the areas of complex compounding being carried out
b. identify CPD needs relevant to these identified competencies and documenting these in the form of a CPD plan
c. undertake CPD activities (including a training program) that address identified continuing professional development needs
d. gain 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 safety risks and requires specific competencies. Pharmacists are encouraged to engage an expert or mentor to assist.

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 guideline 4.3 *Supervision of support staff* and the practice standards listed in these guidelines).

If a pharmacist has not achieved competence or is no longer competent to undertake a specific compounding task/activity, for example if the required training is currently unavailable, this task/activity must not be carried out by the pharmacist until competence is achieved, unless they are supervised by another pharmacist who is competent.

3 Quality assurance

Quality assurance procedures and processes, including continuous quality improvement, are critical to ensure compounded medicines are reproducible and of consistent quality that meets the requirements of relevant standards and guidelines.

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 require remediation as directed by the authorised entity.

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

Guidance

3.1 Sterile medicines

As stated in the Australian Pharmaceutical Formulary and Handbook, when compounding sterile medicines, pharmacists must comply with the principles outlined in one of the following guides/standards, 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.

The compounding of sterile medicines poses significant risks to the public if undertaken improperly. Complying with the principles in one of the above guides/standards can assist in managing risks to patient safety.

Consideration must be given to all relevant factors when planning to compound sterile medicines. This includes:

- the practice setting
- the types of medicines compounded
- the risks identified during the risk assessment process for compounded products outlined in these guidelines
- 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 should 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
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 of community pharmacies, 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 quality standards, practice standards and guidelines listed in these guidelines set out the facility, working environment and equipment specifications needed when compounding medicines. The *Compounding* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook* also provides additional information about facilities, equipment and personnel.

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
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
b. ensuring that the pharmacy is suitably resourced, and that staff members are suitably trained and appropriately supervised.

Ingredients

As outlined in the *Australian Pharmaceutical Formulary and Handbook*:

- All ingredients should be produced by manufacturers with suitably approved quality assurance and quality control procedures, including appropriate licensing and/or certification.
- Australian manufacturers of human medicines should hold a Licence to Manufacture Therapeutic Goods issued by the TGA to manufacture the relevant ingredients (licences are not required for the manufacture of excipient 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 ingredients 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 to confirm its suitability for compounding. For example, excipient ingredients can be tested by a laboratory accredited by the National Association of Testing Authorities (NATA) and active ingredients must be tested at a laboratory licensed by the TGA.

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

* Note for veterinary medicines - overseas manufacturers should hold a certificate of GMP compliance or equivalent accreditation from a regulatory or accrediting authority equivalent to the APVMA.

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 and document 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, cytotoxic medicines or complex compounding). 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 Ingredients

A pharmacist must obtain the necessary evidence to demonstrate that all ingredients comply with the default standards under the Therapeutic Goods Act (monographs in the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia) 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 and quality 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
i. counsel and ensure the patient (or in the case of an animal patient, the owner), or agent, 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 can be formed by consulting 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 (such as adding a flavour) or used as an ingredient (for example, 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 the formulation of a compounded medicine 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. The formulation should be based on published and reputable information, not testimonials or impressions.

The suitability of the formulation 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 (for example, if the use of a preservative is appropriate and supports assigning a longer expiry date). Refer to *Guideline 6 Assigning expiry dates to compounded medicines* for information on assigning a suitable expiry date.

There are several factors to consider when formulating a compounded medicine and the Board has provided guidance on some of these below. For more information, refer to the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

Guidance

5.1 Formulations for which precedents do not exist

Before deciding to compound a medicine for which there is no formulation precedent in a reputable reference and/or there is inadequate published safety, efficacy, pharmacokinetic or clinical data, a pharmacist must document a risk assessment using sound judgement based on up-to-date clinical and pharmaceutical knowledge. Examples of such medicines could include (but are not limited to):

- preparations containing hormones
- 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. If no evidence to justify the decision exists, pharmacists must not compound such medicines.

The pharmacist should also ensure that the patient, or in the case of a veterinary medicine, the animal owner, has been advised that the compounding has taken place under these circumstances.

5.2 Quantity to be supplied

The quantity of compounded medicine supplied should:

- ensure a safe and quality medicine for the duration of the prescribed treatment
- be appropriate for the treatment period determined by the prescriber (or determined by the pharmacist for a non-prescription medicine) and that ensures a safe and quality 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 by a prescriber, this should be confirmed with the prescriber.

Note for animal patients:

In the case of compounded veterinary medicines, a pharmacist may supply more than the quantity required for a single patient when supplied in response to instructions or written order from a veterinarian, where permitted by legislation (such as supply for multiple animals on a property or for supply for use in emergency situations, or supply for the veterinarian's use in practice).

Compounded veterinary medicines are not required to be assessed for quality, safety, efficacy or stability unlike medicines for veterinary use which are manufactured and registered for that purpose. Before compounding medicines in batches, the compounding pharmacist should confirm the applicable expiry date of the medicines and ensure that the quantity that is compounded is the quantity that the veterinary practitioner anticipates will be required for use prior to the expiration date.

Refer to 'Guideline 7 Batch preparation'.

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 evidence supporting the formulation, stability and quality of the modified medicine is available
c. after a risk assessment that supports the modification has been documented

d. after communication with the prescriber has taken place if the modification is requested by the patient.

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

5.4 Risk assessment process for compounded medicines

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

Risk assessment and management processes should 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 to supply a compounded medicine (including repeat prescriptions) and should consider any risks specific to the individual patient. Some risks may not change for subsequent repeat supplies of the medicine. For example, premises-related risks where the premises are maintained to the required standard and may not need to be documented in every risk assessment.

Note for animal patients:

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

5.5 Consistency of supply

The pharmacist should take reasonable steps to assure themselves that the requested medicine has been compounded consistently with previous supplies by using the same ingredients as those used previously, unless there are quality or safety concerns about the previous compounding. The pharmacist should inform the patient that even if the same ingredients are used, there may be a variation in the look or feel of the final medicine due to differences in formulation.

Consistency of supply is particularly important for high-risk medicines such as those with a narrow therapeutic index, or for modified-release preparations. The patient should be made aware that differences in formulation to that of previous supplies could result in changes to the clinical effect of the medicine and have consequences for the patient.

Pharmacists have a professional obligation to ensure the safety of the patient by ensuring the patient can access information about the ingredients in their compounded medicine and should not have ‘secret’ ingredients.

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.
- 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 to patient safety associated with compounded sterile injectable medicines, as outlined in the *Australian Pharmaceutical Formulary and Handbook*, the default expiry date of sterile injectable medicines should be 24 hours or less from the time of compounding (when stored under the recommended storage conditions for the particular medicine) as 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
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 must only be assigned to a compounded sterile injectable medicine if the pharmacist meets all the necessary conditions for such medicines outlined in the *Compounding* section of the current edition of the *Australian Pharmaceutical Formulary and Handbook*.

A pharmacist should 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

Before compounding multiple units of a medicine (that meets the requirements in legislation that permits compounding), a pharmacist may consider preparing a single larger quantity (a batch) in order to supply single units of the medicines for individual patient use.

Batch preparation of compounded medicines is associated with higher risks. These may include a compounding error or contamination potentially affecting a larger number of patients (human or animal).

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

To minimise the risks to patient safety, 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 should 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 9 *Documentation*).

8 Managing risks that may lead to injury

Pharmacists are legally obligated to comply with occupational health and safety standards in accordance with legislation, and are expected to comply with relevant pharmacy 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.

Information 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 that involve occupational health and safety risks, everyone involved should 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.

When entering the details of the compounded medicine into the dispensing system, pharmacists are required to ensure that any ingredients monitored by real time prescription monitoring (RTPM) systems (such as Schedule 8 medicines) are recorded correctly to ensure accurate monitoring.

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

Pharmacists should ensure appropriate documentation about compounding medicines is maintained, 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
e. supports routine reporting of adverse events
f. is stored in a manner that is easily retrievable.

Documentation should clearly demonstrate that all individuals have met their responsibilities of compliance with legislation, practice standards and procedures relevant to compounding.

Additional information on how recalls are regulated can be found on the TGA website.

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

Compounded medicine labels should include:

- the name and strength of each active ingredient (especially if a formula other than a standard pharmacopoeial formula is used) or the pharmacopoeia or *Australian Pharmaceutical Formulary and Handbook* name
- the name and quantity or concentration of any added preservatives
- the name of all inactive ingredients
- the name of the formula as described in a standard pharmacopoeia reference book (where applicable)
- the dose form and quantity supplied
- the date of compounding
- the expiry date
- storage details
- directions for use
- cautionary advisory labels
- a unique number or code that links the compounded medicine with its preparation documentation
- the name and contact details of the compounding pharmacy
- the patient's name or, in the case of an animal, the owner's name and the species of animal (unless exempt by legislation, for example supply of medicine to a veterinary practitioner for emergency use in states or territories where this is permitted).

If it is not possible to fit all the details of the ingredients of a non-pharmacopoeial formula on the dispensing label, a list of the ingredients should also be provided to the patient upon request. Refer to guideline 12 for additional information.

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).

If the compounded medicine is for veterinary use, the label should also specify 'For animal treatment only'.

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 by patients.

Guidance

Verbal counselling, including written information where appropriate or required, should be provided by the pharmacist to facilitate the safe and effective use of the compounded medicine. This should include:

a. an explanation of why a compounded medicine is being supplied, and how this differs to a:
    i. commercially available medicine, which meets TGA requirements, or
    ii. registered veterinary chemical product that meets APVMA requirements
b. instructions on how and when to take, administer or apply the medicine (such as 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
g. any other information that would be appropriate.

Pharmacists should 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.

12 Supporting informed patient choice

Patients have a right to choose where they obtain their medicines and access other pharmacy services. The *Code of conduct* supports good practice and therefore applies to the supply of all medicines including compounded medicines. The code states:

Providing good care includes that you recognise and respect the rights of patients to make their own decisions about their current and future healthcare. (1.1 Providing good care (f)).

The *Australian Charter of Healthcare Rights* describes the rights a patient can expect when receiving healthcare. It addresses principles such as patients having their choices recognised and respected, and making decisions with their healthcare provider, to the extent that they choose and have the capacity to do so.

Patients who request or consent to having their prescriptions exclusively dispensed at a particular pharmacy may choose to withdraw their consent at any time.

Guidance

In the course of their professional practice, pharmacists who offer or agree to enter into arrangements with particular healthcare practitioners or other third parties, must not advise a patient or give the impression that they are obliged to obtain or continue to receive care from the health practitioners who have established the agreement when it is open to the patient to decide where to access their health care[1].

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

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

13 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.

If the adverse event is due to an error (such as in compounding or prescribing), the *Code of conduct* outlines that practitioners have a responsibility to be open and honest in communication with the patient to review what happened and to report appropriately (Section 4.5 Adverse events and open disclosure).

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

Guidance

Pharmacists should report all suspected adverse events (unrelated to an error) to compounded medicines to:

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

This reporting requires appropriate documentation of adverse events.

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 should have access to 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 practitioner 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.

Agent means a person who is acting on behalf of the patient. For animal patients this may include the veterinarian if they are providing the compounded medicine directly to the owner of the animal.

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 a medicine.

Commercial medicine means for the purpose of these guidelines, a medicine entered on the ARTG or a medicine approved for import and supply under s19A. 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 therapeutic product for a specific patient in response to an identified need or, the extemporaneous preparation and supply of a therapeutic product in a hospital, if 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. 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 in response to an identified need 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 (refer to 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.

Patient means for the purpose of these guidelines a person receiving healthcare from a registered health practitioner or an animal receiving healthcare from a veterinarian. It includes clients and consumers and for animals it includes the owner of the animal. 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.

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.

Supervising pharmacist for the purpose of these guidelines is a pharmacist holding general registration who is responsible for the 'day to day' direct supervision of staff involved in the compounding of medicines.

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

Interpretation

In these guidelines, unless the context requires otherwise:

- 'must' means that, in the view of the Board, the appropriate standard of practice requires that the relevant course of action be taken. 'Must not' has a corresponding meaning.
- 'should' means that, in the view of the Board, the appropriate standard of practice requires that the relevant course of action generally be taken and that there may be certain circumstances in which after proper consideration a difference course may be taken. 'Should not' has a corresponding meaning.
- 'may' means that, in the view of the Board, a number of different courses of action may be available to the practitioner, depending on the circumstances. The practitioner must exercise good judgment and have regard to the particular circumstances when deciding the appropriate course of action in each case.

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*

The Code of conduct

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

Additional information

Pharmacy Board of Australia *Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists*

Pharmacy Board of Australia *FAQ for pharmacists on the compounding of medicines*

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

Review

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These guidelines will be reviewed at least every five years.

From 1 October 2024, these guidelines replace *Guidelines on compounding of medicines* published 1 March 2015 and 1 August 2017 for the section *Compounding of sterile injectable medicines*.