Consultation report

October 2024

Guidelines on compounding of medicines

Contents

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Background

The Pharmacy Board of Australia (the Board) recently consulted on a draft revised *Guidelines on compounding of medicines.* This was done as part of its regular review of standards, codes and guidelines to ensure they remain relevant, contemporary and effective.

Preliminary consultation on the draft revised guidelines was held between 7 November 2022 and 9 January 2023 with targeted stakeholders. During this initial consultation, we tested the Board's proposals and sought feedback on clarity of the proposals and the draft consultation materials. Public consultation was held between 30 May and 24 July 2023. The draft revsied guidelines, consultation paper and other supporting documents can be found on the Board's website at the past consultations webpage.

The Board carefully considered all feedback. We would like to thank the many individuals, organisations and professional associations who thoughtfully reviewed the proposals and provided feedback to our consultation.

This report summarises the feedback received from this wide-ranging consultation and provides information about how these responses were considered in the development of the finalised *Guidelines on compounding of medicines* which were published on 5 August 2024 ahead of implementation on 1 October 2024.

Principles that informed the review

When reviewing the guidelines, the Board considered the following:

- Objectives and guiding principles of the National Scheme as set out in the Health Practitioner Regulation National Law (the National Law)
- The Regulatory principles of the National Scheme
- Policy Direction 2019-02[1]
- Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025, and
- Ahpra's procedures for the development of registration standards, codes and guidelines.

As a result of the review guided by the above documents, the Board has published updated guidelines that:

- promote professionalism and support practitioners
- reduce unnecessary duplication of regulation
- articulate outcomes that protect the public
- can be complied with by individual practitioners
- are proportionate to the risks posed and not excessive
- do not produce guidance that duplicates existing legal obligations or professional practice standards
- were reached through an open, transparent and consultative process.

Submissions

A total of 95 submissions were received from organisations and individuals. 21 submissions were received during preliminary consultation, and 74 during public consultation. Submissions requested for publication can be reviewed here.

Submissions were received from regulatory stakeholders (such as government and pharmacy premises authorities), consumers, pharmacy member organisations, veterinary stakeholders, other organisations and individual pharmacists.

[1] Requirement to consult with patient safety bodies and health care consumer bodies on every new and revised registration standard, code and guideline

Guiding pharmacists on the safe compounding of medicines

The finalised *Guidelines on compounding of medicines* (the guidelines) aim to inform registered pharmacists and the community about the Board's expectations of pharmacists when compounding medicines. They highlight that all compounding must be compliant with legislation and practice standards relevant to compounding.

The *Therapeutic Goods Regulations 1990* set out the exemptions relevant to pharmacists in relation to the compounding of medicines for human use. This includes that most compounded medicines are not required to be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied, provided they are compounded by a pharmacist for a particular person, for therapeutic application to that person.

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. Compounding should only occur after consideration of the matters highlighted, and in the circumstances specified, in the guidelines. This is both to protect the public and promote public confidence in the safe delivery of health services by pharmacists.

As the Board's guidance needs to apply in a continually changing environment, the focus of the guidelines is on principles that support safe compounding of medicines by pharmacists.

The Australian Pharmaceutical Formulary and Handbook (APF) was updated in February 2024 and provides a completely revised compounding section with separate chapters dedicated to the compounding of sterile medicines and hazardous medicines. In revising the guidelines, we considered the additional detailed information contained in the APF and aimed to not duplicate information contained in this essential reference that supports good practice by pharmacists and foundational learning by pharmacy students.

How we managed feedback

We considered all consultation feedback in the context of the regulatory requirements for compounding medicines, while ensuring the guidance we developed remained within our remit under the National Law. We were able to incorporate much of the feedback in the guidelines, but were not able to make changes in response to all feedback.

In accordance with s4 of the National Law, we had regard to the objectives and guiding principles of the National Scheme. The main guiding principle is that:

(a) 'the following are paramount— (a) protection of the public; (b) public confidence in the safety of services provided by registered health practitioners and students' (in Queensland, Victoria, South Australia and the Territories)

(b) 'the protection of the health and safety of the public must be the paramount consideration' (in New South Wales).

Public safety was our focus in considering the feedback received and finalising the guidelines.

Highlighting common medicine supply pathways

The draft revised compounding guidelines included additional content on medicine supply pathways to consider before deciding if it is appropriate to compound a medicine (Guideline 1 When to compound medicines) and included an amended definition of a commercial medicine. The aim of the amended definition was to highlight a range of common pathways for accessing medicines that may be appropriate and in certain circumstances, preferential to compounding medicines. These include s19A, Special Access Scheme (SAS) and the Authorised Prescriber (AP) pathway.

Most submissions agreed that the new content on medicine supply pathways was clear and helpful, however there was mixed support for the revised definition of a commercially available medicine. We heard that including pathways such as the SAS can be problematic, as in theory any medicine can be supplied under SAS. This could make it difficult for a pharmacist to determine if an alternative medicine is

available. Although the Therapeutic Goods Administration (TGA) has approved the use of these medicines, the medicines themselves are ‘unapproved’.

In response to the feedback, we decided to revise the definition of a commercially available medicine to the following:

‘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 available for supply under s19A are ‘approved’ medicines and the Board decided to retain these in the definition. Although the Board has not included medicines available via the SAS or AP pathways in the definition of a commercial medicine, if a medicine available via these pathways is readily available and appropriate for a patient, it may be a suitable alternative to a compounded medicine.

Formula for the compounded medicine

The draft revised guidelines proposed that a copy of the formula of the compounded medicine (listing all active ingredients and their strengths, and all inactive ingredients) must be provided to the patient when requested. The proposed guidance intended to contribute to public safety by making patients aware of the ingredients in their medicine and support patient choice in where they access their compounded medicine.

There was mixed support for requiring that a patient be able to access a copy of the formula for their compounded medicine. Most stakeholders supported transparency and patient choice however some stakeholders provided feedback that ‘formula’ could be taken to include the method of preparation which should not be required to be provided to the patient. Some stakeholders also submitted that a formula is the intellectual property of the compounding pharmacist.

We have amended the draft revised guidance to clarify that a patient must be provided with a list of ingredients (rather than specifying the formula) for their compounded medicine when requested. The list of ingredients should include:

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

Providing patients with information about the ingredients in their compounded medicine will support patient choice and awareness and safer patient outcomes (such as enabling identification of an ingredient responsible for an adverse reaction).

Compounding of veterinary medicines

The draft revised guidelines included content specific to medicines compounded for animal patients. Feedback from stakeholders was helpful to ensure that the Board’s guidance was clear and could be successfully applied within the regulatory framework for treating animals in different states and territories.

Some stakeholders made suggestions that we decided not to incorporate which included:

- a risk assessment by the pharmacist should not be required for each request for a compounded medicine for animal patients
- the pharmacist should not be required to provide counselling as that is the role of the veterinarian
- as the Board does not regulate veterinarians it should not be providing guidance on compounding of veterinary medicines.

Regarding risk assessments, the Board maintains that a pharmacist is still required to undertake a risk assessment when compounding a medicine for an animal patient which will include consideration of:

- product related risks
- premises related risks
- personnel related risks.

The guidelines state that for animal patients, the patient-specific risk assessment for the supply of a compounded medicine may need to be undertaken in collaboration with the veterinarian requesting the medicine, who would also need to consider patient related risks in the course of their practice..

The pharmacist has responsibilities in relation to counselling which cannot be abrogated. The guidelines advise that counselling can be provided to the patient or the patient's agent. This would enable situations where the pharmacist is providing relevant information to either the owner of the animal, or to the veterinarian who may be administering the medicine to the animal or providing it the animal's owner.

Although the Board does not regulate veterinarians it does regulate pharmacists and therefore it is within its remit to provide guidance to pharmacists undertaking the compounding of veterinary medicines.

Professional practice profile

The Board consulted on its proposal to retire its published *Professional practice profile for pharmacists undertaking complex compounding*. This was proposed as a professional practice profile should be practitioner specific, describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Individuals should develop their own practice profile by selecting the relevant competencies from the competency standards and customising them for use in their own practice setting.

There was widespread support for the Board's proposal to retire the *Professional practice profile for pharmacists undertaking complex compounding*, therefore we have decided to take this action.

Consumer fact sheet

The Board developed a fact sheet about compounded medicines to support consumer participation in the public consultation. However, feedback showed support for the Board to also publish the fact sheet on its website as a resource for pharmacists and members of the public.

As a result of feedback, we have made some minor amendments to the consumer fact sheet and published it on the Board's website.

Other feedback

Several stakeholders proposed minor amendments to the guidelines to improve clarity which we incorporated.

Some stakeholders suggested changes to the guidelines that we have decided not to incorporate. After careful review, the changes we decided not to make included suggestions that:

a. did not support the principle of protection of the public

b. are not in line with legislation

c. are not in the remit of the Board to provide guidance on (for example, premises requirements in legislation administered by another entity).

Next steps

We will review and update any supporting resources such as FAQs to assist pharmacists in understanding the finalised guidelines. Updates on any new or revised resources will be provided in our newsletter.