



GUIDELINES ON PRACTICE-SPECIFIC ISSUES

September 2015

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Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They provide guidance to pharmacists in relation to a range of practice-specific issues not set out in legislation or a registration standard.

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

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 holding the following types of registration:

- general
- provisional, or
- limited.

These guidelines do not apply to pharmacists holding non-practising registration or to students. However, students should become familiar with these guidelines prior to undertaking supervised practice placements.

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. Additionally, pharmacists are expected to be aware of and comply with the profession's standards and guidelines (including any other standards or guidelines referred to in those documents), as relevant to their scope of practice and type of registration. The pharmacy practice standards

and guidelines can be accessed on the website of the relevant professional bodies:

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

Non-compliance with these guidelines and the relevant practice standards and guidelines may be notified to the Board for appropriate action under the National Law. Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. 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 and guidelines 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).

Summary of guidelines

These guidelines address various pharmacy practice matters, including those which relate to specific services provided by some pharmacists or at some pharmacies. Particular reference is made to drugs of abuse. As patterns of drug abuse change over time, the content of these guidelines is expected to be revised as needed.

Guidelines

1 Reference texts for pharmacists

Access to contemporary references is essential to the practice of pharmacy.

On its website, the Board provides an up-to-date list of essential references for pharmacists (document titled: *Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists)*). This list includes the

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primary reference the *Australian Pharmaceutical Formulary and Handbook* which contains Internet addresses on a wide variety of subjects. The list also includes Australian Commonwealth, state and territory acts and regulations, and a number of additional references, which are accessible free of charge on the Internet.

Guideline

Pharmacists must be able to readily access contemporary works of professional reference in either conventional or electronic forms. The information is to be immediately available to the pharmacist during the clinical assessment, reviewing, dispensing and counselling processes.

In addition to accessing the references listed in this guideline during the clinical assessment, reviewing, dispensing and counselling processes, pharmacists should use additional references specific and relevant to their scope of practice (refer to the Board's *Guidelines on compounding of medicines* for examples of additional reference texts for compounding pharmacists). Consideration should also be given to accessing reference material which provides information in the Australian context. At any one time, pharmacists may need to use more than one reference to ensure that all current and relevant information is accessed.

While it is the pharmacy owner's responsibility to provide the resources, it is the responsibility of the pharmacist to ensure prescribed references are readily available and accessed when required. As part of the premises approval process, the state or territory pharmacy premises registering authority or responsible body may prescribe particular references in addition to those shown on the Board's website.

2 Drugs of abuse

As part of their continuing professional development, pharmacists are expected to have a contemporary knowledge of the drugs that are subject to abuse or misuse, both generally and in their own localities.

Guideline

Keeping abreast of the Australian professional literature

and the public media relating to drugs of abuse, and engagement with colleagues, is strongly recommended.

Requests for drugs to which this guideline relates are to be treated cautiously because of manipulative behaviour on the part of drug seekers. A genuine therapeutic need is to be established by careful questioning. A pharmacist supplying potential drugs of abuse to a patient must comply with all relevant state or territory, and Commonwealth legislation, Pharmacy Board of Australia *Guidelines for dispensing of medicines*, and established practice standards and guidelines.

Evidence of any developing trend in the use of drugs of abuse should be communicated to the authorities, such as the state or territory health authority, and to colleagues and professional bodies, for example a notable increase in the presentation of prescriptions for a particular medicine subject to abuse.

3 Pseudoephedrine

Pseudoephedrine is used as a precursor in the illicit manufacture of amphetamines. It is extracted from products in which pseudoephedrine is the sole active ingredient or is one of several active ingredients. Additional obligations, which vary between states and territories, apply to pharmacists when responding to requests for pseudoephedrine-containing products.

Guideline

Requests for pseudoephedrine are to be treated cautiously to limit the risk of the product being diverted for illicit use/manufacture. A genuine therapeutic need is to be established by careful questioning, including when requested on prescription.

Only one proprietary pack is to be supplied at a time unless there are exceptional circumstances clearly demonstrated by the customer or communicated by the prescriber, additional documentation of which should be kept. The sale of multiple packs of pseudoephedrine-containing products (other than in exceptional circumstances and when appropriately prescribed by an authorised prescriber) and failure to comply with the local regulations applying to Schedule 3 poisons (Pharmacist Only Medicines) and these guidelines may be considered as unprofessional conduct.

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Stock levels should be minimal in accordance with the sales history of the pharmacy and any relevant security issues. Bulk supplies should be avoided and any reserve stock kept out of public view.

The Board endorses the use of a real-time online monitoring system (e.g. Project STOP), as a means of assisting the pharmacist in determining whether pseudoephedrine should be supplied when a person requests it, noting that this may also involve communicating suspicious requests to the section of the police that deals with drug crimes. All purchases, including those on prescription, should be entered on this system.

4 Supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines)

In addition to any statutory requirements applicable to the supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines), the Board has regard to the relevant practice standards and guidelines, and any substance-specific protocols and quality-assurance standards.¹

Guideline

Staff members need to be trained to ask specific questions of intending purchasers of Pharmacy Medicines and Pharmacist Only Medicines. This should include (but is not limited to) questioning the purchaser about other medication they are taking, including complementary and alternative medicine. Any queries relating to Pharmacy Medicines or unscheduled medicines that arise from the person's response should be referred to a pharmacist. All requests relating to Pharmacist Only Medicines must be referred to a pharmacist.

Pharmacists are reminded that particular statutory obligations relating to the supply of Pharmacist Only Medicines must be observed. The pharmacist must be satisfied that there is a therapeutic need. This means more than agreeing to supply the medicine on request, or merely asking patients if they have used the medicine previously and know how to use it.

Only one proprietary pack of Pharmacy Medicines and Pharmacist Only Medicines is to be supplied at a time, unless there are exceptional circumstances clearly demonstrable by the customer, additional documentation of which should be kept. Caution should be exercised when considering requests for supply of multiple packages, particularly for drugs subject to abuse or misuse, for example codeine-containing products and products containing pseudoephedrine (also refer to Guideline 3 *Pseudoephedrine*). Failure to comply with local jurisdiction regulations applying to Pharmacy Medicines and Pharmacist Only Medicines and these guidelines may be considered as unprofessional conduct.

5 Complementary and alternative medicines

Complementary and alternative medicine and accompanying advice are often supplied by pharmacists and their staff in the ordinary course of pharmacy practice. A pharmacist may also hold an additional qualification to practise as a complementary and alternative medicine practitioner, as separate and distinct from their practice as a pharmacist.

Guideline

When complementary and alternative medicine is provided at a pharmacy, pharmacists should provide products of proven safety and quality. Relevant accompanying advice should be offered to assist patients in making a well informed choice regarding treatment with a complementary or alternative medicine, which should include available information on the potential benefits and harms, and whether there is sufficient evidence to support its proposed use. Where appropriate, pharmacists should incorporate details of the supply of complementary and alternative medicines in the dispensing record and where possible, in the patient's health record.

A pharmacist who is also a complementary and alternative medicine practitioner may provide these services in a pharmacy. When consulting clients privately in this capacity, this should be done:

- in a room that is separate from the dispensary, general trading and professional services areas, and where required by law, approved by the state or territory pharmacy premises registering authority

¹ Minor amendment made on 28 April 2017. Previously stated "In addition to any statutory requirements applicable to the supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines), the Board has regard to the *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy* (produced by the Pharmaceutical Society of Australia) and any substance-specific protocols and quality-assurance standards."

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- in accordance with state and territory regulatory requirements, and
- while another pharmacist is in charge of the pharmacy.

6 Allied health, and complementary and alternative therapy when practised by other persons in the pharmacy

An allied health practitioner or complementary and alternative medicine practitioner may practise in a pharmacy premises as either an employee of the pharmacy business, or as a practitioner working independently under a leasing arrangement with the pharmacy business subject to state or territory pharmacy premises registering authority approval.

Guideline

If an allied health practitioner or complementary and alternative medicine practitioner practises in a pharmacy as an employee of the pharmacy business, the activities and services provided must complement the role of the pharmacist and should be provided by suitably qualified practitioners. Proprietors and individual pharmacists supervising pharmacy employees are responsible for the dispensing of complementary and alternative medicine and any accompanying advice provided by the employees of the pharmacy business.

Pharmacists must ensure that allied health practitioners and complementary and alternative medicine practitioners who are employees of a pharmacy business do not:

- compound or otherwise dispense any medicines at the pharmacy, or
- use any dispensing labels relating to the pharmacy.

Where appropriate, pharmacists should incorporate details of the supply of complementary or alternative medicines in the dispensing record and where possible, in the patient's health record. Separate records of the supply must not be kept by employees of the pharmacy.

In the case where a pharmacist rents or leases consulting rooms in a pharmacy to an allied health practitioner or complementary and alternative medicine

practitioner subject to any state or territory pharmacy premises registering authority approval, that person may not be an employee of the pharmacy business and must use labels unrelated to those of the pharmacy.

7 Screening and risk assessment

This guideline relates to pharmacists providing in-pharmacy health screening.

Guideline

Pharmacists who conduct screening and risk assessment tests are expected to follow established practice and quality-assurance standards, including the relevant guidelines issued by professional associations and state or territory pharmacy premises registering authorities.

8 Raw materials not approved for human use in medicines

Manufacturers of analytical reagents (ARs) do not usually sanction the use of their products for therapeutic use, despite the implicitly high level of purity.

Guideline

Pharmacists should only supply or use after careful consideration, chemicals and other substances for therapeutic purposes that have not been approved by Australian health authorities for use in humans. When pharmacists use such substances in a medicine, it is prudent to keep records of the supply to and from the pharmacy (also refer to the Board's *Guidelines on compounding of medicines*).

Pharmacists are reminded of their obligation to comply with any state and territory requirements in relation to raw materials.

9 Supply of tobacco and alcohol products

Guideline

The sale or supply of tobacco products, alcoholic beverages, home brewing or alcohol distilling kits by a pharmacist is inconsistent with the practice of pharmacy and is considered as unprofessional conduct within the meaning of the National Law.

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Definitions

A **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.

Practice means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession.

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

Unprofessional conduct, as defined in the National Law, means professional conduct that is of a lesser standard than that which might reasonably be expected of a health practitioner by the public or a practitioner's professional peers.

References

Pharmacy Board of Australia *Guidelines for dispensing of medicines*

Pharmacy Board of Australia *Guidelines on compounding of medicines*

Review

Date of issue: 2 September 2015

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Date of review: September 2020

These guidelines will be reviewed at least every five years.

From 7 December 2015, these guidelines replace the Pharmacy Board of Australia *Guidelines on practice-specific issues* published 12 August 2010.