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Guidelines for dispensing of medicines



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Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the National Law.¹ The guideline provides guidance to those registered in the profession in relation to a matter of professional practice, not set down in the legislation or a registration standard, which can be used in proceedings under the National Law as evidence of what constitutes professional conduct or practice for the health profession.

The relevant sections of the National Law are attached.

Who needs to use these guidelines?

These guidelines are developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to all pharmacists registered in the following categories:

- general
- provisional
- limited

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

In addition to complying with these guidelines, pharmacists are encouraged to maintain an awareness of the standards published by the profession, and relevant to their area of practice and category of registration. In considering notifications (complaints) against pharmacists, the Board will have regard to relevant professional practice and quality-assurance standards, depending on the nature of the matter under consideration. Standards should be accessed on the websites of the professional bodies:

- Pharmaceutical Society of Australia (PSA)
- The Society of Hospital Pharmacists of Australia (The SHPA)
- The Pharmacy Guild of Australia (The PGA)

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

Pharmacists must comply with all legislation relevant to the practice of pharmacy in the jurisdiction where the dispensing occurs.

Summary of guidelines

This set of guidelines centre on safe dispensing and labelling of medicines, and on providing a good pharmaceutical service. They also address the training and roles of dispensary assistants.

Guidelines

1 Dispensing precaution – safety of prescriptions

A pharmacist must take reasonable steps to ensure that the dispensing of a medicine in accordance with a prescription or order is consistent with the safety of the person named in that prescription or order.

Guidelines

In dispensing a prescription, a pharmacist has to exercise an independent judgment to ensure the medicine is safe and appropriate for the patient, as well as that it conforms to the prescriber's requirements. If there is any doubt, the prescriber is to be contacted.

In conforming to the above principle, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history, and other relevant circumstances need to be taken into account.

2 Dispensing multiple repeat prescriptions at one time

The simultaneous supply of multiple quantities of a particular medicine (i.e. the supply of multiple repeats at once) may not be in accordance with the prescriber's intention and is contrary to good pharmaceutical practice.

Guidelines

The practice of supplying multiple quantities of a particular medicine at a single dispensing, or of supplying multiple quantities to a patient even though a prescriber may have provided a 'blanket request/approval' to a pharmacist to do so, is contrary to the National Medicines Policy and Quality Use of Medicines principles. It does not promote best pharmacy practice in relation to regular review of therapy and effective provision of medicine information, which assists in minimising medication misadventure. The supply of multiple repeats at the one time is permitted under Regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960, and each prescription for multiple supplies should be so endorsed. Dispensing of multiple quantities of any prescriptions should only occur at the specific direction of the prescriber on each occasion,

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¹ The National Law is contained in the schedule to the Health Practitioner Regulation National Law Act 2009 (Qld).

unless exceptional circumstances exist to the satisfaction of the pharmacist, and an appropriate notation is made to that effect on the prescription and in the dispensing record.

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3 Facsimile and scanned prescriptions

A pharmacist may dispense a prescription transmitted by facsimile or scanned copy in accordance with the guidelines.

Guidelines

A pharmacist, who has taken reasonable steps to satisfy themselves that the prescription is bona fide and in accordance with relevant State or Territory legislation, may dispense a prescription transmitted by facsimile or scanned copy in advance of receiving the original prescription. An original prescription must still be obtained and retained in accordance with poisons legislation.

4 Internet, mail-order dispensing and other indirect supply of medicines

The Board views the indirect supply of medicines, such as internet and mail-order dispensing, as less than the optimal way of delivering a pharmacy service because communication may be compromised. The Board recognises, however, that there are circumstances where these forms of communication are necessary in, or appropriate to, the patient's circumstances (e.g. in remote areas).

Guidelines

A pharmacist supplying medicines indirectly to a patient must comply with all relevant State or Territory, and Commonwealth legislation, the Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines*, and established practice and quality assurance standards.

5 Extemporaneous dispensing (compounding)

Pharmacists should refer to the Board's new *Guidelines on compounding of medicines* published in March 2015 and in effect from 28 April 2015.

6 Incident records

Dispensing errors, significant other errors, omissions, incidents, or other noncompliances, including complaints of a noncommercial nature arising both within and external to the pharmacy, may be the subject of investigation. Pharmacists should therefore follow a risk management procedure, including appropriate record keeping.

Guidelines

The record is to show when the incident was recorded, when it occurred, who was involved (both actual and alleged), the nature of the incident or complaint, what actions were taken and any conclusions. If contact was made with third parties, such as government departments, prescribers, lawyers or professional indemnity insurance companies, details of the conversation should be recorded.

Regardless of how serious the incident may appear, comprehensive detailed records need to be kept.

The record should be kept for three years because of the delayed nature of some forms of litigation.

7 Labelling of dispensed medicines

Pharmacists are to label dispensed medicines in accordance with any statutory provisions and these guidelines with a view to:

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- maximising the benefits of the therapy
- improving the patient's understanding of the treatment.
- enhancing compliance
- minimising adverse effects.

Relevant legislation in force in the jurisdiction in which the pharmacist is practising should be followed.

Guidelines

7.1 Labels

The placement of the dispensing label on the product is largely determined by the design of the medicine package and the manufacturer's label.

The dispensing label is to be firmly attached to the immediate container (including each component of multiple-therapy packs) unless the immediate container is so small or is so constructed that the label would compromise the patient's ability to use the medicine (e.g. metered aerosols and some eye drops). In such instances, the label should be attached to the primary pack or alternatively, purpose-designed labelling tags or 'winged' labels may be used.

The label should be clearly and legibly printed in unambiguous and understandable English; other languages that are accurate translations of the English may be used in addition to English.

The special needs of patients with disabilities, such those with poor eyesight, should be accommodated and the patient adequately informed.

The label should be placed to leave visible any of the manufacturer's statements that may be important to the patient, including the expiry date, storage conditions and where possible, the name and strength of the drug.

7.2 Label content

The label is to include the following:

- the brand and generic names of the medicine, the strength, the dose form and the quantity supplied; for extemporaneously prepared medicines and medicines not dispensed by count, the name and strength of each active ingredient, and the name and strength of any added preservatives or the name of the formula as described in a standard reference book
- specific directions for use, including frequency and dose
- the patient's name or, in the case of an animal, the owner's name and the kind of animal
- the date of dispensing or supply

- the dispenser's (and if different, the checking pharmacist's) initials
- a unique identifying code
- the name, address and telephone number of the pharmacy or pharmacy department at which the prescription was dispensed
- storage directions (where important) and expiry date (where applicable)
- the words 'Keep out of reach of children'.

7.3 Ancillary labels

Some ancillary labels are mandatory — these are listed in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). The routine use of other ancillary labels in the *Australian Pharmaceutical Formulary and Handbook* is recommended having regard to each patient's circumstances.

8 Counselling patients about prescribed medicines

Patients have the right to expect that the pharmacist will counsel them privately about their medicines, but the patient reserves the right not to be counselled. The pharmacist should make every effort to counsel, or to offer to counsel, the patient whenever a medicine is supplied. Patient counselling is the final checking process to ensure the correct medicine is supplied to the correct patient.

Lack of counselling can be a significant contributor in dispensing errors and their detection. In this regard, the Board endorses the current patient counselling guidelines produced by PSA and The SHPA, including the use of 'Consumer Medicines Information' (CMI) leaflets.

Guidelines

More detailed advice is especially important when certain drugs are supplied and in certain circumstances. Examples include:

- the taking of medicines that can sedate
- the taking of medicines that have a narrow therapeutic index
- unusual dose forms (e.g. fentanyl patches)
- unusual frequency of use (e.g. alendronate, methotrexate)
- when a new medicine is prescribed
- when there is a change in the dose or frequency of administration
- when the brand of medicine has changed

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- when the medicine is a controlled drug with each supply of medicine for which there are valid reasons for regular reinforcement of information (e.g. teratogenics or cytotoxics; major contraindications; special patient needs, such as language preference, vision, hearing or cognitive impairment, or cultural issues)
- at regular intervals (e.g. six monthly) for medicines used for long-term therapy
- when the medicine is for a child;
- if the patient is taking many medicines
- when there is an acute illness or event (e.g. hospital admission).

In the case of patients taking repeat prescriptions, counselling provides the opportunity to inquire if the patient is taking the medicine correctly, if the medicine is having the desired outcome or if there are unwanted effects. It offers a further opportunity to detect any errors.

The contents of a CMI, such as mention of certain diseases or side effects, may cause confusion or even alarm among some patients; therefore, the pharmacist may need to work through the CMI with the patient in order to relate its contents to the individual circumstances.

Face-to-face counselling is the best way of communicating information about medicines, but where that is not possible or practicable, written information and/or a telephone call are recommended while making sure that the information is provided directly to the patient.

9 Privacy and confidentiality

Commonwealth, State and Territory privacy laws set out the privacy principles applicable to health providers. Pharmacists should ensure that all pharmacy services are provided in a manner that respects the patient's privacy requirements, and is in accordance with relevant professional and quality assurance standards.

Guidelines

Information about a person that a pharmacist obtains in the course of professional practice is confidential and may be disclosed only:

1. with that person's permission
or
2. to other persons authorised to the extent of the latter person's lawful jurisdiction
or
3. on a court order
or

4. if, in the pharmacist's opinion, it is in the patient's best interest to divulge pertinent information to another health practitioner who is treating the patient.

Authorised persons include:

- a Pharmacy Board of Australia officer or an Australian Health Practitioner Regulation Agency (AHPRA)-appointed investigations officer
- an officer of the State or Territory pharmacy authority
- a person authorised under the State or Territory poisons law (including a member of the police force to the extent authorised)
- a member of an enforcement agency in accordance with the *Privacy Act 1988* (Cwth), or State or Territory privacy laws
- an authorised officer of Medicare Australia for the purposes of examining prescriptions supplied as pharmaceutical benefits under the *National Health Act 1953* (Cwth)
- an authorised officer of State or Territory statutory authorities that administer laws of work or road traffic-related insurance.

Particular care should be exercised if other official bodies seek information. State or Territory privacy authorities should be contacted in cases of uncertainty.

The name or details of a therapeutic product (medicines and devices) should not be identified in information given to other than the person for whom it was intended, unless the person waives that right. Examples of persons to whom information may be inadvertently disclosed could include a person paying a family account or to third party organisations (including service companies) that process accounts, and organisations collecting statistical data.

The inadvertent disclosure of the identities of patients' medicines (and therefore the patients' medical conditions) to third parties is to be avoided.

10 Dispensing errors and near misses

All reasonable steps need to be taken to minimise the occurrence of errors.

Guidelines

Good practice dictates that there should be a systematic approach in dealing with errors and near misses so that lessons can be learned from them and corrective action taken.

Pharmacists are to use barcode scanners when dispensing medicines at dispensing stations in pharmacies and pharmacy departments, and are to be used for the

intended purpose. They are an aid to, but not a substitute for, minimising selection errors.

Routine checking throughout the dispensing process is necessary, with particular emphasis being attached to the final check at the time of actual supply and at the time of dispatch of medication to wards. Counselling of the patient or carer about their medicines provides an additional check.

Adequate time must be allowed to dispense properly every prescription (see also Section 11, 'Pharmacists' workloads').

Arrangements should be in place to minimise distractions during the dispensing process, which can lead to dispensing errors. Pharmacists dispensing medicines need to ensure that the operation of the pharmacy dispensary is such that the risk of errors is minimised to their professional satisfaction.

11 Pharmacists' workloads

Pharmacists should ensure that the individual workloads under which they operate are at reasonable and manageable levels to:

- ensure the safety of the patient
- provide an appropriate pharmaceutical service in an accurate, professional and timely manner
- cope with fluctuations in workflow.

Patients' unrealistic expectations in relation to time taken to dispense the prescription, or the need to meet imposed maximum prescription waiting times are considered not conducive to the provision of such a service.

Pharmacist owners and managers are to have in place suitable quality-assurance systems and procedures for the management of pharmacist workload.

Guidelines

The Board recommends that if dispensing levels are in the range of 150–200 scripts per day, consideration needs to be given to the use of trained dispensary assistants and/or intern pharmacists to assist the pharmacist. If the workload exceeds 200 scripts a day, additional pharmacists or dispensary assistants may be required to ensure adequate time is allowed to dispense properly every prescription in accordance with Board guidelines, taking into account:

- predictable spikes in activity during specific times, days or months
- mix of prescription types (e.g. repeats, dose administration aids, harm-minimisation therapy, cytotoxics, intravenous additives)

- advanced dispensing technologies
- pharmacy-dispensing mode (e.g. forward pharmacy)
- staff experience and familiarity with systems
- use of auxiliary staff (e.g. intern pharmacists)
- other dispensing-related responsibilities (e.g. counselling, patient medication profiles, medication reviews, adherence programs)
- other nondispensing responsibilities (e.g. Schedule 3 medicines, preceptor responsibilities and patients' expectations).

The Board acknowledges that pharmacists may be required to dispense above this rate in unforeseen circumstances, such as staff shortage due to sudden illness or unpredicted demand. The Board recognises that in such circumstances pharmacists can take effective short-term measures to deal with the workload while continuing to meet their professional obligations.

Note: This guideline is subject to review following further consideration.

12 Dispensary assistants/dispensary technicians and hospital pharmacy technicians

Pharmacists may be assisted in the dispensing of medicines in the dispensing area of a pharmacy business or pharmacy department, in accordance with the guidelines, by suitably trained persons. The descriptions, 'dispensary assistant', 'dispensary technician' or 'hospital pharmacy technician' do not apply to a pharmacist, a provisionally registered intern pharmacist or a registered pharmacy student.

For the purposes of these guidelines, 'dispensary assistant' and 'dispensary technician' have the same meaning. In different industrial relations circumstances, both terms are used.

Guidelines

The pharmacist in charge of the pharmacy business or department is responsible for ensuring that dispensary assistants' or dispensary technicians' functions are limited to those functions that do not require them to exercise professional judgement or discretion. All relevant State or Territory, and Commonwealth legislation, Pharmacy Board of Australia *Guidelines for Dispensing of Medicines*, and established practice and quality assurance standards are to be met.

The pharmacist is responsible for assessing the appropriateness of the medicines in relation to the full medication history, the final check of dispensed medicines

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and the counselling of the consumer (refer Standard 5 of PSAs Professional Practice Standards)

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Pharmacists should ensure that dispensary assistants or dispensary technicians undertake and complete a recognised training course that provides them with the skills and knowledge to, under the direct personal supervision of a pharmacist, assist in the selection, processing and labelling of prescription medicines. An individual pharmacist must not supervise more than two dispensary assistants or dispensary technicians engaged in the selection, processing and labelling of prescription medicines at a time. Other trained dispensary assistants or dispensary technicians can be engaged in duties that do not require direct supervision outside of this ratio (e.g. in dispensary stock control or preparing dose administration containers; refer to Quality Care Pharmacy Program's 'Standards').²

Note: This guideline is subject to review following further consideration.

13 Return of unwanted medicines

Pharmacist owners or managers are encouraged to arrange to accept for safe disposal of unwanted medicines from the public through their pharmacy's participation in available programs, such as the Return of Unwanted Medicines (RUM) project.

Guidelines

Detailed procedures relating to the return and disposal of unwanted medicines, including Schedule 8 medicines, needles, other sharps and cytotoxic products, are available at <http://www.returnmed.com.au>.

Any unwanted medicines are preferably placed immediately and without examination in an approved disposal bin that is stored to prevent unauthorised access. It is not necessary to empty any medicine containers or remove tablets from their immediate wrappers.

When a pharmacist collects unwanted medicines from a person's residence (e.g. in the course of a home medication review), the unwanted medicines are to be placed in a suitable interim container (as supplied by the RUM project), before being transferred to a pharmacy for disposal.

² <http://www.guild.org.au/qcpp/content.asp?id=807>

Attachment 1

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Extract of relevant provisions from the *Health Practitioner Regulation National Law Act 2009*

Part 5, Division 3 Registration standards and codes and guidelines

Section 39. Codes and guidelines

A National Board may develop and approve codes and guidelines—

- (a) to provide guidance to the health practitioners it registers; and
- (b) about other matters relevant to the exercise of its functions.

Example. A National Board may develop guidelines about the advertising of regulated health services by health practitioners registered by the Board or other persons for the purposes of section 133.

Section 40. Consultation about registration standards, codes and guidelines

- (1) If a National Board develops a registration standard or a code or guideline, it must ensure there is wide-ranging consultation about its content.
- (2) A contravention of subsection (1) does not invalidate a registration standard, code or guideline.
- (3) The following must be published on a National Board's website—
 - (a) a registration standard developed by the Board and approved by the Ministerial Council;
 - (b) a code or guideline approved by the National Board.
- (4) An approved registration standard or a code or guideline takes effect—
 - (a) on the day it is published on the National Board's website; or
 - (b) if a later day is stated in the registration standard, code or guideline, on that day.

Section 41. Use of registration standards, codes or guidelines in disciplinary proceedings

An approved registration standard for a health profession, or a code or guideline approved by a National Board, is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a health practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the health profession.

Contents edit

Edit made to page 2: Guideline 5 *Extemporaneous dispensing (compounding)* previously published in these 2010 guidelines was removed following implementation of the Board's *Guidelines on compounding of medicines* on 28 April 2015.