
# Consultation paper on guidelines

## comprising

## Guidelines on dispensing medicines

## Guidelines on specialised supply arrangements

## Guidelines on practice specific issues

If you wish to provide comments on this paper, please lodge a written submission in electronic form, marked 'Attention: Chair, Pharmacy Board of Australia' to natboards@dhs.vic.gov.au by close of business on Monday 14 June 2010. Unfortunately, late submissions cannot be accepted.

Please note that your submission will be placed on the Board's website unless you indicate otherwise.

# Contents

# Introduction

This consultation paper has been developed under the requirements of the *Health Practitioner Regulation National Law Act 2009* (the National Law). The National Law empowers national boards to develop and approve codes and guidelines to provide guidance to the health practitioners a board registers and about other matters relevant to the exercise of boards' functions.

The National Law includes a requirement for national boards to ensure there is wideranging consultation on proposed registration standards, codes and guidelines.

The Board has previously consulted on proposed registration standards to apply from 1 July 2010. Once finalised and approved by the Board these guidelines will come into force from 1 July 2010.

# Guidelines for dispensing of medicines

## Introduction

These draft guidelines have been developed by the Pharmacy Board of Australia under section 39 of the *Health Practitioner Regulation National Law Act 2009.* 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 Act 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:

a) general
b) provisional
c) limited

Pharmacists holding non-practising registration who are proprietors of pharmacy businesses must also ensure compliance with these guidelines in their pharmacy businesses. 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 expected to be aware 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 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
- The Society of Hospital Pharmacists of Australia

*(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).*

## Summary of guideline

These 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 that the drug is apt for the patient as well as that it conforms to the physician'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 drugs, the patient's illness and drug 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 e.g. 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 is contrary to the National Medicines Policy and may deprive the consumer of regular review and provision of medicine information which assist in minimising medicine misadventure. Exceptional circumstances, such as those under Regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960, may permit the supply of multiple repeats.

### 3 Facsimile prescriptions

A pharmacist may dispense a prescription transmitted by facsimile, subject to the Guidelines.

*Guidelines*

Except in accordance with the next paragraph, the medicine should not be supplied until the pharmacist has possession of the original prescription (or valid PBS repeat authorisation) and is satisfied that the dispensed medicine agrees with it.

Where the facsimile prescription:

1. has been transmitted from a pharmacy depot, hospital or aged care facility; and
2. where clear standing instructions have been provided to responsible staff at these places that:

    (a) the medicines so supplied are not consumed by the patient until the pharmacist has checked the original prescription: and
    (b) the pharmacist has specifically authorised the supply or administration of the medicine,

the medicine may be supplied from the facsimile.

Visible fax "noise" has been identified as a source of error such as introducing or omitting decimal points.

Subject to State law, if a facsimile of the prescription has been transmitted by the prescriber confirming verbal instructions, the medicine may be supplied before the actual prescription is in the hands of the pharmacist.

## 4 Internet and mail order dispensing

The Board views Internet and mail order dispensing as less than the optimal way of delivering a pharmaceutical 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.

With the rise in electronic commerce and communication, it is essential to remember that:

1. prescriptions for Schedule Four and Schedule Eight poisons must be written by medical and certain other health practitioners who are registered in an Australian jurisdiction; and
2. the supply of Schedule Three poisons, except on prescription, by the Internet or by mail order is not permitted because of the regulatory requirement that the supply must be personal on the part of the pharmacist.

*Guidelines*

The patient and the pharmacist are to have one another's contact details.

The pharmacist is to obtain from the patient sufficient clinical information, including the patient's current medication, to ensure safe dispensing recognising that in some cases, the patient may also attend a local pharmacy in person for other medication. An offer of verbal counselling must be made on each occasion.

The supply of a Consumer Medicines Information (CMI) leaflet is recommended whenever a new medicine is supplied.

Standard operating procedures that set out the steps in the receipt and dispatch of medicines are required to ensure that the correct medicines reach the patient for whom they were prescribed. The procedures are to include mention of any special packaging or storage requirements while the parcel is in transit and the exclusion of any reference to the identity of the contents.

## 5 Extemporaneous dispensing

In the absence of any formulation published in a standard reference, there should be good clinical and pharmaceutical evidence to support the quality, safety, efficacy and rationality of any extemporaneous formulation. Evidence is best obtained from peer-reviewed journals rather than being solely based on testimonials and impressions.

Particular care should be exercised in the case of medicines for which there are no precedents in standard references. Examples are oral and topical hormone preparations, those containing substances whose use has not been approved in Australia for therapeutic use, and preparations that contain well-established drugs for oral use but for which there are inadequate safety and efficacy data when the same drug is used topically.

An extemporaneous preparation should be used only in circumstances where a commercial product is unavailable or unsuitable.

The Board has regard to the *Australian Pharmaceutical Formulary and Handbook's* statement, "Extemporaneous Dispensing".

*Guidelines*

Starting materials are to comply with pharmacopoeial standards, have validated expiry dates and be obtained from a reputable licensed supplier. If the material is not the subject of a pharmacopoeial monograph, the supplier should be asked to supply a standard.

The composition of the medicine is to be based on sound pharmacological, clinical and pharmaceutical principles. Ingredients and processing conditions that would result in potentially toxic or ineffective preparations must be avoided.

Expiry dates are determined from the date the medicine is prepared. Because the medicine is intended for immediate use or following short-term storage, the expiry dates are based on criteria different from those applied in commercial manufacture.

Pharmacists should consult and apply drug-specific and general stability documentation and literature when available, taking into account the properties of the drug, its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.

Equipment should be appropriate to the quantities to be made up having regard to possible complications arising from scaling up the quantity prepared for one patient.

In the case of specialised or novel formulations that are frequently prepared, such as those that include high potency substances, samples should be submitted from time to time to a competent analytical laboratory for assay.

Modified-release formulations should only be made up if there is credible *in vivo* and *in vitro* data that support the quality, safety, efficacy, rationality and relevance of the precise formulation.

Adding substances to commercially manufactured medicines is discouraged because the full formulation details of the latter are not generally available.

Protective clothing and equipment are required when handling drugs of high milligram potency, such as hormones. These include non-shedding disposable laboratory coats or overalls with elasticised cuffs and closures up to the neck; particulate respirators (N95 rated) or HEPA filtered (P100) respirator masks; nitrile gloves; hair and beard coverings and shoe covering. A powder containment cabinet that meets Australian Standard *AS 2252.1 – 2002: Biological safety cabinets (Class I) for personnel and environment protection* is required for operator protection. Australian Standard *AS 2252.1 - 2002* must be read in conjunction with *AS/NZS 2647 – 2000: Biological safety cabinets – Installation and use,* which describes recommended practices for the installation and use of the cabinets. Base line and periodic pathology monitoring is also required.

Sterile medicines should be made up only if:

1. the premises meet the Australian Standard for clean rooms;
2. sterilisation equipment operates in accordance with the manufacturer's specification and the performance is validated;
3. procedures are fully documented and implemented; and
4. staff are suitably trained in the preparation of sterile products.

*Notes*

*Extemporaneous dispensing in community pharmacies*

In jurisdictions that:

1. have legislation that complements the *Therapeutic Goods Act 1989* (Cwth); or

2. where the *Therapeutic Goods Act 1989* (Cwth) applies directly as in the case of trading corporations,

the following general rules relating to the manufacture and supply of therapeutic goods are:

1. the goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied, unless they are "exempt goods"; and
2. the premises where the medicines are manufactured must be licensed, unless the person carrying out the manufacturing is an "exempt person".

"Exempt goods" include "medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person".

"Exempt persons" include "pharmacists in relation to the manufacture of therapeutic goods produced by the pharmacist" in a pharmacy where the pharmacist practises and is open to the public; or on the premises of a dispensary conducted by a Friendly Society; or on the premises of a private hospital for supply (other than by wholesale) on or from those premises.

The following table summarises the requirements.

| CIRCUMSTANCES | ARE THE GOODS REQUIRED TO BE ENTERED ON THE ARTG? | ARE PREMISES REQUIRED TO BE LICENSED? |
|---|---|---|
| Medicine made up for a named patient. Patient-specific label and records of supply kept. [1] | No | No |
| Medicine made up and supplied for general sale only from the pharmacy where it was made up.[2] | Yes | No |
| Medicine made up and supplied to another person for on-supply.[3] | Yes | Yes |

1. The first situation presents no difficulties and applies to medicines dispensed on prescription and to medicines that the pharmacist prescribes on his or her own motion. The usual recording and labelling requirements apply.

2. The second situation applies when a pharmacist decants from a bulk pack (of either a commercial product or something that he or she makes) into smaller containers with the pharmacy's own label for supply other than as in the previous paragraph.

3. In the third situation, the pharmacist is no different from any other manufacturer in that the premises would require licensing from the Therapeutic Goods Administration. The Code of Good Manufacturing Practice would have to be implemented.

Therapeutic goods that are prepared by pharmacists employed by a public hospital or public institution for supply in hospitals or public institutions within the State are exempt from having to be entered on the ARTG and the hospital or institution is not required to hold a manufacturing licence.

## 6 Incident records

The Board recommends that a diary (electronic or paper) be kept for the purpose of contemporaneously recording incidents that may give rise to queries from the authorities or are complaints of a non-commercial nature.

*Guidelines*

The record will 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.

The more serious the incident, the more the detail that should be recorded.

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

## 7 Labelling of dispensed medicines

Dispensed medicines are to be labelled in accordance with any statutory provisions and in accordance with these guidelines with a view to maximising the benefits of the therapy, improving the patient's understanding of the treatment, enhancing compliance and minimising adverse effects.

*Guidelines*

### 7.1 Labels

The 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; metered aerosols and some eye drops are examples. In such instances, the label should be attached to the primary pack or alternatively, purpose-designed labelling tags 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 additionally.

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:

1. 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;
2. directions for use;
3. the patient's name or, in the case of an animal, the owner's name and the kind of animal;
4. the date of dispensing or supply;
5. the dispenser's initials;
6. a unique identifying code;
7. the name, address and telephone number of the pharmacy or pharmacy department at which the prescription was dispensed;
8. storage directions (where important) and expiry date (where applicable); and
9. 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 Drugs and Poisons*. 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

A patient has the right to expect that the pharmacist will counsel him or her privately about his or her medicine but the patient reserves the right not to be counselled. Every effort should be made to counsel, or to offer to counsel the patient whenever a medicine is supplied.

*Guidelines*

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

- the taking of drugs that can sedate;
- the taking of drugs that have a narrow therapeutic index;
- unusual dose forms (e.g. fentanyl patches);
- unusual frequency of use (e.g. alendronate, methotrexate);
- when a new drug is prescribed;
- when there is a change in the dose or frequency of administration;
- if the patient is taking many drugs; or
- an acute illness.

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 supply of Consumer Medicine Information (CMI) leaflets or other counselling aids is recommended. 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 and State privacy laws set out the Privacy Principles applicable to health providers.

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:

1. a Pharmacy Board of Australia officer;
2. an officer of the State pharmacy authority;
3. a person authorised under the State poisons law (including a member of the police force to the extent authorised);
4. a member of an enforcement agency in accordance with the *Privacy Act 1988* (Cwth) or State privacy laws;
5. an authorised officer of Medicare Australia for the purposes of examining prescriptions supplied as pharmaceutical benefits under the *National Health Act 1953* (Cwth); and
6. an authorised officer of State statutory authorities that administer laws of work- or road traffic- related insurance.

*Guidelines*

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

Members of staff at a pharmacy and pharmacy departments are to be trained about the need to observe confidentiality in all their dealings with the public.

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. Ensuring that dispensed medicines are not transferred to checkouts in open baskets for other people to look at or comment on, is essential. Similarly, dispensed medicines that are waiting collection should be stored in a manner that prevents third parties from relating them to the person for whom the medicines are intended.

Dispensary counters should be designed so that privacy is not compromised and in such a way that members of the public cannot view private information.

## 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.

Routine checking throughout the dispensing process is necessary with particular emphasis being attached to the final check at the time of actual supply when the patient is counselled about his or her medicines.

Bar code scanners are mandatory 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.

Adequate time must be allowed to dispense properly every prescription (see also Workloads).

Distractions, such as clients talking to the pharmacist while prescriptions are being dispensed, are to be avoided by suitable design of premises.

## 11 Workloads

Workloads must be kept at reasonable and manageable levels to ensure the safety of the patient and to ensure that the work environment is conducive to good pharmaceutical practice. Proprietors or managers must ensure that conditions are in place to meet the public's right to receive an appropriate pharmaceutical service in an accurate, professional and timely manner.

Consumers' expectations have reached a stage when many people expect immediate attention irrespective of the amount of work required to dispense that person's medicines, contact with prescribers, or that other prescriptions have been lodged before theirs. Consumers should be encouraged to return or invited to use a waiting area rather than standing at the serving counter.

*Guidelines*

In-pharmacy practices of imposing on staff maximum prescription waiting times and any associated bullying or threats are unacceptable to the Board. The Act prohibits inciting unprofessional conduct.

A pharmacy should be staffed to meet the expected workload. As a benchmark, not less than one full-time equivalent pharmacist dispensing an average of 150 prescriptions over a 9.00am to 6.00pm day is regarded as the *minimum* staffing level. Attention should be paid to predictable spikes in activity during specific times, days or months. Sustainable workload may also be affected by other factors such as dispensing technologies, staff familiarity with systems and other non-dispensing responsibilities.

The preparation of each take-away dose of methadone and each administration of an opioid substitution medicine is counted as being the equivalent of one prescription.

If dispensing levels are in the range of 150 to 200 prescriptions daily, a trained dispensary assistant may assist but if the workload exceeds 200 daily, an additional pharmacist is required for at least part of the day.

The Board acknowledges that a pharmacist may be required to dispense above this rate in unforseen circumstances such as staff shortage due to sudden illness. The Board recognises that in such circumstances the pharmacist can take effective short term measures to allow him or her to deal with the workload and meet his or her professional obligations.

## 12 Dispensary assistants/dispensary technicians or hospital pharmacy technicians

Suitably trained persons may assist a pharmacist in the dispensing of medicines in the dispensing area of a pharmacy business or pharmacy department, in accordance with the guidelines. The descriptions, "dispensary assistant", "dispensary technician" or "hospital pharmacy technician" do not apply to a 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.

### 12.1 Responsibilities of the pharmacist in charge

The pharmacist regularly and usually in charge of the pharmacy business or pharmacy department is responsible for ensuring the guidelines are complied with.

*Guidelines*

1. A pharmacist must supervise a dispensary assistant or dispensary technician.

2. A pharmacist must not supervise more than one dispensary assistant or dispensary technician actually engaged in dispensing prescriptions at a time. The number of dispensary assistants or dispensary technicians employed in a pharmacy business or a pharmacy department must not exceed at any one time, the number of pharmacists present in the dispensary of that pharmacy business or pharmacy department.
3. Dispensary assistants' or dispensary technicians' functions are limited to those that do not require them to exercise professional judgement or discretion.
4. Written records of a dispensary assistant's or dispensary technician's duties are to be maintained [see: 12.3].
5. Documentation verifying that a dispensary assistant and dispensary technician has completed an approved course must be available at all times when a person is working in that capacity.
6. A dispensary assistant or dispensary technician must possess a valid certificate of competency from a registered training organisation and on-going validation of the employer for each of the following areas where he or she assists a pharmacist in dispensary operations:

   non-sterile preparation;
   sterile preparation;
   cytotoxic preparation; or
   clerical and administrative components of clinical pharmacy services.

7. Notwithstanding the dispensary assistants' or dispensary technicians' duties, a pharmacist must review the patient's history; check the dispensed medicine for accuracy and that it complies with the prescriber's intentions, ensure that it is safe for the patient and counsel the patient.

12.2 Training of dispensary assistants/dispensary technicians

Pharmacists may employ persons as dispensary assistants/technicians provided those persons have completed a course of training, consistent with the Australian National Training Authority (ANTA) course in their chosen area of practice.

*Guidelines*

1. The person may be employed if he or she is actually enrolled in the next available course relevant to their area of employment and scheduled to take place within the next six months, or is currently undertaking such a course.
2. Persons who, before 1 July 2010, have assisted the pharmacist in the dispensing of prescriptions must enrol in a course consistent with the ANTA framework course by 1 January 2011 and have satisfactorily completed the course by 30 June 2012.
3. If the person is to undertake non-sterile, sterile or cytotoxic preparative work, the person must have completed the relevant course and have current validation in the area of practice.
4. The validation is current for 12 months and initially will be issued by the course provider and thereafter by the pharmacist regularly and usually in charge following an assessment of competence in the specific area of practice.
5. The Board will consider for recognition a course of suitable duration for dispensary assistants conducted by providers who can demonstrate they have the resources, background and support to provide a suitable course and submit appropriate course information, consistent with the ANTA framework of the relevant national competency standards for dispensary assistants, for approval by the Board.

12.3 Duties of dispensary assistants/dispensary technicians

Dispensary assistants/dispensary technicians are subject to personal supervision by a pharmacist in carrying out their duties.

*Guidelines*

The duties are:

1. performing routine maintenance procedures on computers;
2. assisting in dispensary stock control, including stocktaking, ordering, unpacking, checking and putting stock away;
3. checking expiry dates and rotating stock;
4. pre-packing stock;
5. assisting in dispensary administration;
6. assisting in the dispensing process, including selecting stock; preparing dispensing labels; attaching cautionary and advisory labels (provided important patient information on the manufacturer's pack is not obscured and that the pharmacist can check the manufacturer's label); arrange all documentation and medicines in such a way that permits the pharmacist to check the prescription;
7. setting out dispensed medicines into dose administration containers, provided the setting out is checked by a pharmacist;
8. preparing extemporaneous, cytotoxic and non-sterile medicines, provided the assistant has completed course consistent with the ANTA framework and has current validation so to do; and
9. carrying out clerical and administrative functions in a clinical setting.

The duties are not:

1. receiving prescriptions over the telephone;
2. discussing with or counselling patients about any aspect of the content of a prescription (other than Medicare and similar details);
3. deciding the brand to be used in dispensing generic prescriptions;
4. issuing a dispensed medicine unless the pharmacist has reviewed the patient's medication history, checked the dispensed medicine for accuracy and compliance with the prescriber's intentions and ensured that the supply is consistent with the patient's safety; and
5. selecting or altering the storage conditions of medicines.

12.4 Summary of requirements of training and duties

| DESCRIPTION | DUTIES | TRAINING | REMARKS |
|---|---|---|---|
| Dispensary assistant | As per text (above). | Certificate of Level 3 National Competency Standards for Pharmacy Assistants – Assist in Dispensary Operations from a course provider approved by the Board. | Valid from date of issue. |
| Approved to assist in non-sterile preparation | As per text (above) plus assist in preparation of medicines prescribed for a patient requiring extemporaneous non-sterile preparation, including the reconstitution of oral liquids. | As for dispensary assistant plus completion of an approved course in non-sterile preparation. | Certificate to assist in non-sterile preparation initially provided by a course provider valid for 12 months then annual validation by the pharmacist in charge. |
| Approved to assist in sterile preparation | As per text (above) plus assist in preparation of medicines prescribed for a patient requiring extemporaneous non-sterile or sterile preparations. | As for dispensary assistant plus completion of an approved course in sterile preparation. | Certificate to assist in non-sterile and sterile preparation initially provided by a course provider valid for 12 months then annual validation by the pharmacist in charge. |

| | | | |
|---|---|---|---|
| Approved to assist in cytotoxic preparation | As per text (above) plus assist in preparation of medicines prescribed for a patient requiring extemporaneous non-sterile or sterile preparations including cytotoxic products. | As for dispensary assistant plus completion of an approved course in non-sterile preparation, sterile preparation and in cytotoxic preparation. | Certificate to assist in non-sterile, sterile and cytotoxic preparation initially provided by a course provider valid .for 12 months then annual validation by the pharmacist in charge. |
| Approved to assist in clerical and administrative components of clinical pharmacy services | As per text (above) plus assist in the delivery of clinical pharmacy services not involving professional pharmaceutical judgement. | As for dispensary assistant plus completion of an approved course in clerical and administrative components of clinical pharmacy services. | Certificate to assist in clerical and administrative components of clinical pharmacy services initially provided by a course provider valid for 12 months then annual validation by the pharmacist in charge. |

12.5 Written records

The pharmacist regularly and usually in charge of a pharmacy or pharmacy department who employs any dispensary assistants must keep written records about their work.

*Guidelines*

The records are to include:

1. the names of each dispensary assistant employed;
2. the details of each assistant's training;
3. the details of each certificate of competency where applicable;
4. a job description for the assistant employed at the premises that includes those tasks that the assistant is *not* to undertake; those tasks the assistant may undertake; and instruction as to the supervision and conduct of assistants; and
5. a copy of the job description must be readily available or displayed at all times in the premises in a place where the assistant is able to refer to it during his or her normal work in the dispensary or pharmacy department; and be provided personally to each dispensary assistant employed at the premises.

## 13 Return of unwanted medicines

The Board encourages pharmacists to accept for safe disposal unwanted medicines from the public.

*Guidelines*

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 (for example, in the course of a home medication review), the unwanted medicines are to be placed in a suitable interim container before being transferred to the disposal bin.

The bins are collected by an approved waste disposal contractor.

## Attachment 1

## 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.

# Guidelines on practice specific issues

## Introduction

These draft guidelines have been developed by the Pharmacy Board of Australia under section 39 of the *Health Practitioner Regulation National Law Act 2009.* 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 Act 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:

a) general
b) provisional
c) limited

Pharmacists holding non-practising registration who are proprietors of pharmacy businesses must also ensure compliance with these guidelines in their pharmacy businesses. 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 expected to be aware 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 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
- The Society of Hospital Pharmacists of Australia

*(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).*

## Summary of guideline

These guidelines address miscellaneous subjects and settings facing pharmacists with particular reference 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 References

Up to date works of reference are essential to the practice of pharmacy and must be readily accessible.

*Guidelines*

Pharmacists must be able to access contemporary works of professional reference in either conventional or electronic forms. The information is to be immediately available to the pharmacist during the dispensing process.

The Board's website includes an up to date list of essential references.

The *Australian Pharmaceutical Formulary and Handbook* includes Internet addresses on a wide variety of subjects.

All Commonwealth and State acts and regulations are accessible on the Internet.

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

### 2 Drugs of abuse

As part of their continuing professional knowledge, 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.

*Guidelines*

Keeping abreast of the Australian professional literature and the public media and engagement with colleagues is recommended.

Requests for drugs to which this policy relates are to be treated circumspectly because of manipulative behaviour on the part of drug seekers. A genuine therapeutic need is to be established by careful questioning.

Evidence of any developing trend should be communicated to the authorities, such as the State health authority, and to colleagues and professional bodies.

### 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. Extra obligations, which vary between States, devolve on pharmacists in managing requests to supply products containing it.

*Guidelines*

Only one package is to be supplied at a time unless there are exceptional circumstances, documentation of which should be kept. The sale of multiple packs of pseudoephedrine-containing products (other than in exceptional circumstances) and failure to comply with the local regulations applying to Schedule 3 poisons and these guidelines may be considered as unprofessional conduct that invites disciplinary action.

Pharmacists should ensure that stock levels are to be kept to no more than one week's supply and any reserve stock is to be kept out of public view.

Suspicious requests for pseudoephedrine products should be communicated to that section of the police that deals with drug crimes.

The Board endorses the use of Project STOP as a means of assisting the pharmacist in determining whether pseudoephedrine should be supplied when a person requests it.

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

In addition to any statutory requirements, the Board has regard to the *Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy,* produced by the Pharmaceutical Society of Australia and any substance-specific protocol.

*Guidelines*

Staff need to be trained to ask specific questions of intending purchasers of Schedule 2 and Schedule 3 poisons and any queries that arise from the person's response should be referred to a pharmacist.

The particular statutory obligations on the supply of Schedule 3 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 the patient if he or she has used the medicine previously and knows how to use it.

## 5 Complementary and alternative therapy when practised by pharmacists

A pharmacist who is acting in the capacity of an alternative therapies consultant is to carry out this function as separate and distinct from the practice of pharmacy in approved pharmacy premises.

*Guidelines*

A pharmacist in an approved pharmacy practising complementary and alternative therapies such as naturopathy, homoeopathy or herbalism that involve a private consultation with a client is to do so in a room that is:

1. separate from the dispensary, general trading area or professional service area; and
2. approved by the state pharmacy authority.

Another pharmacist is to be in charge of the pharmacy when the first pharmacist is acting as a complementary therapist.

The supply of complementary medicines and any accompanying advice in the ordinary course of pharmacy practice does not imply that the pharmacist is practising complementary medicine.

## 6 Complementary and alternative therapy when practised by other persons in the pharmacy

The dispensing of medicines and any advice by the employees of a pharmacy business are responsibilities of the proprietors and individual pharmacists.

*Guidelines*

Pharmacists need to ensure that naturopaths and other therapists who are employees of a pharmacy business do not compound or otherwise dispense any medicines at the pharmacy, use any dispensing labels relating to the pharmacy or maintain exclusive records.

Subject to State pharmacy authority approval, a pharmacist may rent or lease consulting rooms in a pharmacy to a naturopath or other person provided the person is not an employee of the pharmacy business. In such a case, the person must use labels unrelated to those of the pharmacy.

## 7 Pathology testing

Pharmacists who conduct pathology or other screening tests are expected to follow the guidelines issued by the Pharmaceutical Society of Australia.

## 8 Substances not approved for human use in medicines

The supply or use of chemicals and other substances for therapeutic purposes that have not been approved by Australian health authorities for use in humans should only be used by pharmacists after careful consideration.

*Guidelines*

Manufacturers of Analytical Reagents (AR) do not usually sanction the use of their products for therapeutic use, despite the implicitly high level of purity.

When pharmacists use such substances in a medicine, it is prudent to keep records of the supply to and from the pharmacy.

## 9 Supply of tobacco products

The sale or supply of tobacco products by a pharmacist is inconsistent with the practice of pharmacy and is considered as unprofessional conduct within the meaning of the Act.

# Attachment A

**Guideline 1 References**

Proposed list of references to be accessed by pharmacists during the course of practice to be published on the Pharmacy Board of Australia website:

**Current editions** in the form of a published document (hard copy) **or via electronic** means such as computer of the following should be accessed by pharmacists:

**a the Australian Pharmaceutical Formulary and Handbook (APF)**

**b the Australian Medicines Handbook**

**c a reference work on prescription products e.g.**
- MIMS Annual with bimonthly addenda or e-MIMS
- AusDI Advanced.

**d a Drug Interactions reference (updated at least quarterly).** e.g.

- AusDI Advanced
- Drug Interaction Facts – Facts and Comparisons
- Drug Interactions Analysis and Management, Hansten and Horn
- eMIMS Drug Alert Interactions
- Micromedex
- Stockley's Drug Interactions online
- Lexi-Interact Online

**e a reference work on therapeutics e.g the Therapeutic Guidelines Limited Series**

- Analgesic
- Cardiovascular
- Dermatology
- Endocrinology
- Gastrointestinal
- Neurology
- Oral and Dental
- Palliative Care
- Psychotropic
- Respiratory
- Rheumatology

**f a paediatric pharmacopoeia published by an Australian teaching hospital**

**g. an evidence-based reference work on complementary and alternate medicines e.g:**
- **Herbs and Natural Supplements: An evidence based guide, Braun and Cohen**
- **Herbal Medicines: A Guide for Health Professionals, Newell, Anderson and Phillipson**

**The following can be accessed electronically via websites:**

**h copies of the legislation controlling the practice of pharmacy:**
• the Health Practitioner Regulation National Law Act 2009
• Drugs and Poisons legislation

**i the Pharmacy Board of Australia Guidelines**

**j the Merck Manual of Diagnosis and Therapy, Merck Sharp and Dohme**

# Attachment 1

## 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.

# Guidelines on specialised supply arrangements

## Introduction

These draft guidelines have been developed by the Pharmacy Board of Australia under section 39 of the *Health Practitioner Regulation National Law Act 2009.* 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 Act 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:

a) general
b) provisional
c) limited

Pharmacists holding non-practising registration who are proprietors of pharmacy businesses must also ensure compliance with these guidelines in their pharmacy businesses. 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 expected to be aware 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 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
- The Society of Hospital Pharmacists of Australia

*(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).*

## Summary of guideline

These guidelines are written in recognition of the increased demand for dose administration containers and, where used in association with them, automated dose packaging systems. Also addressed is advice on dealing with the supply of medicines to be issued periodically.

## Guidelines

### 1 Dose administration aids

Dose Administration Aids (DAAs) may be used for selected patients where the benefits of compliance with a medication regime outweigh the disadvantages inherent in the use of the DAA.

*Guidelines*

An inherent disadvantage with DAAs is that each solid dose form is not individually identified and there is the risk that a filling error may persist for the duration of a DAA's use.

The filling of DAAs is repetitive yet it requires close and systematic concentration to minimise the risk of error. The role may be delegated to suitably trained pharmacy students and interns and dispensary assistants, and the work subjected to checking by a pharmacist. Sufficient space and time, freedom from interruption and good lighting are necessary for safe performance of the task. The area where the work is carried out must be tidy and orderly. Adequate breaks are necessary owing to the mechanistic nature of the task. The ability to review the patient's medication history is essential.

Tablets and capsules may be distributed into the compartments, preferably using forceps, or transferring them with the aid of a spatula and tablet counting tray or pressing them from their foil wrappers.

It is sufficient to wash the hands with soap and water regularly and thoroughly and to dry them with a paper towel or an air dryer before, during and at the end of the session. In hospitals and other establishments where microbiological control is more critical, the establishment's policies should be observed; this will typically require the use of a skin disinfectant. Latex surgical gloves may be used but they may give rise to allergy. Skin disinfectants, such as chlorhexidine, pose the risk of skin sensitivity developing.

All reusable components of DAAs will require cleaning and thorough drying.

The label on the DAA is to identify clearly the name of the patient, the name and address of the pharmacy, the name, strength and dose form of the medicines, the directions for use and the date of filling. In appropriate circumstances, a photograph of the patient may be attached to the DAA. Where cautionary and advisory labels are needed, these can be attached directly to the DAA or provided on a separate sheet. A product identification option to assist nurses and carers is recommended.

A record of each filling should be generated under the patient's name showing the date of filling, the initials of the person who filled it and the medicine's name and dose. The filling record should be retained for at least 6 months.

Procedures should be established to indicate how changes of medication, dose or frequency are recorded.

### 2 Automated dose packaging systems

Automated dose packaging systems may be used to prepare and pack medicines into unit dose packaging for use by patients.

*Guidelines*

Pharmacists who use dose packaging machines must ensure:

1. there is a cleaning and maintenance protocol that is adhered to;

2. testing is undertaken at the start of each day and at any other time as may be operationally required;
3. any person using the machine has received initial and on-going training in its use;
4. the machine is operated in a clean environment away from the dispensing bench and the dispensing computer, and where the temperature is controlled by an air conditioner to ensure the temperature is below 25˚C;
5. the patient's right to privacy is understood and that if a third party is involved in the packing of the dose administration container, the patient or agent must so consent;
6. the labelling of the container in which any strip packs are placed meets any statutory requirements and the Board's guidelines; and
7. the records maintained at the pharmacy include the batch number, the expiry date, the packing date and the initials of the pharmacist or dispensary assistant who is responsible. [Note: If a dispensary assistant packs the container, the pharmacist must also initial the packing];
8. there is a written procedure describing the use of the machines;
9. a written quality assurance program to include the refilling of bulk canisters.

A pharmacist who uses an automated dose packaging system to pack sachets or similar packs on behalf of another pharmacist may need licensing by the Therapeutic Goods Administration in jurisdictions that have laws to complement the *Therapeutic Goods Act 1989* (Cwth).

### 3 Periodic administration of medicines

Where the patient or the prescriber so requests, a pharmacist should be prepared to retain the patient's medicines for periodic administration to the patient.

*Guidelines*

The medicine is to be dispensed in accordance with the prescription and any legal requirements, and retained in the dispensary.

One or more doses are supplied or administered in accordance with the patient's or the prescriber's request.

The patient's consent should be obtained where possible but there are circumstances where this is not possible or practicable.

The patient should sign for the dose or doses of the medicine so supplied or administered in cases where there is concern about potential or actual substance abuse or misuse, safety or false representation. This record is also signed or initialled and dated by the pharmacist who supplies or administers the periodic quantity.

The medicine is to be administered discreetly so that the patient's privacy is not compromised.

Specific requirements apply to opioid substitution and antagonist therapy.

# Attachment 1

## 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.