Guidelines on specialised supply arrangements

Pharmacy Board of Australia

Contents

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 expected 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 services outlined in these guidelines are provided.

Summary of guidelines

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

Pharmacists may provide dose administration aids (DAAs) for selected patients to assist in the safe and effective administration of a patient's medicines and improved adherence. In addition to the Board's *Guidelines for Dispensing of Medicines*, the Board has regard to established practice and quality assurance standards, including the DAA service standards and guidelines issued by PSA.

Guidelines

Dispensed medicines in a DAA 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 patients understanding of the treatment, enhancing compliance and minimising adverse effects.

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, 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 current list of medicines and medication history is essential, and pharmacists need to consider the stability of medicines being packed in a DAA and identify those not suitable for packing in a DAA.

Tablets and capsules should be distributed into the compartments in such a way as to prevent contamination and not to pose any health or safety risks to the person doing the filling. Appropriate hygiene procedures need to be followed prior to, during and following the filling process.

Components of a DAA that are reusable should be maintained in a clean condition, suitable for use with medicines.

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

The label on the DAA should maximise compliance, promote usability and minimise error. It should identify clearly the name of the patient, the name and address of the pharmacy, the name[2], 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, those of the pharmacist who checked it (if not filled by a pharmacist), those of the person who hands out the pack, and the medicine's name and dose. The filling record should be retained for at least six months.

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

Note: This guideline will be reviewed following consideration of the DAA service planned for introduction through the Fifth Community Pharmacy Agreement.

2 Automated dose packaging systems

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

Guidelines

Pharmacists who use automated dose packaging machines must ensure:

- there is a cleaning and maintenance protocol that is adhered to
- testing is undertaken at the start of each day and at any other time, as may be operationally required
- any person using the machine has received initial and ongoing training in its use
- 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
- 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
- the labelling of the container in which any strip packs are placed meets any statutory requirements and the Board's guidelines
- the records maintained at the pharmacy include the batch number, the expiry date, the packing date and the initials of the pharmacist, pharmacy student, intern or dispensary assistant who is responsible *(note: if other than a pharmacist packs the container, the pharmacist must also initial the packing after checking)*
- there is a written procedure describing the use of the machines, including maintenance and error records
- there is a written quality assurance program to include the refilling of bulk canisters.

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

The supply pharmacist is responsible for ensuring the packing pharmacist has an accurate and current medicine chart for the medicines to be packed, as well as being responsible for the Quality Use of Medicines support for the patient.

The packing pharmacist is responsible for ensuring packs are prepared in a timely and accurate manner according to the most recent medicine chart.

The Board considers that it is the supplying pharmacist who carries the ultimate responsibility for all aspects of the supply, including accuracy and provision of medicines' information relating to DAAs prepared by a third-party packing facility.

3 Periodic administration of medicines (staged supply)

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. Consideration also needs to be given to staged supply services covered by State or Territory regulations.

Guidelines

The periodic administration of medicines, including methadone and buprenorphine, should be provided in accordance with State or Territory regulations according to the prescriber's request. The patient's consent should be obtained where possible and the medicine should be administered with consideration of the patient's privacy.

[2] Best practice is to include both active ingredient and brand name, but when circumstances necessitate, such as space limitations, the active ingredient/Australian approved name should be used.

The patient and the prescriber should be informed of the pricing arrangements for the service so that they can make an informed decision about the service.

Note: This guideline will be reviewed following consideration of the final report of the Fourth Community Pharmacy Agreement Review of Staged Supply of PBS Medicines.

Date of issue: 12 August 2010

Date of review: These guidelines will be reviewed at least every three years

Last reviewed:

Last updated: 1 March 2012

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.