

GUIDELINES ON DOSE ADMINISTRATION AIDS AND STAGED SUPPLY OF DISPENSED MEDICINES

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GUIDELINES ON DOSE ADMINISTRATION AIDS AND STAGED SUPPLY OF DISPENSED MEDICINES

Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They provide guidance to pharmacists in relation to the supply of medicines to patients using dose administration aids and the staged supply of dispensed medicines.

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

Who needs to use these guidelines?

These guidelines were developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to all pharmacists holding the following types of registration:

- general
- provisional, or
- limited.

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

What happens if I do not comply with these guidelines?

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

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

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

Non-compliance with these guidelines and the relevant practice standards and guidelines may be notified to the Board for appropriate action under the National Law. Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications (complaints) against pharmacists, the Board will give consideration to whether a breach of these guidelines has taken place. The Board will also have regard to the legislation and practice standards and guidelines relevant to pharmacy practice.

Further information for pharmacists regarding the possible outcomes of notifications is available on the website of the Australian Health Practitioner Regulation Agency (AHPRA) (www.ahpra.gov.au).

Summary of guidelines

These guidelines were developed in recognition of the increased demand for dose administration aids (DAAs) 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 DAAs for selected patients to assist in the safe and effective administration of a patient's medicines and to enhance 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

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the Pharmaceutical Society of Australia, and The Society of Hospital Pharmacists of Australia *SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer*. These standards should be considered as part of the process of determining whether the provision of a DAA to a patient is appropriate.

Guideline

Medicines which are requested to be packed into a DAA must, prior to packing, be dispensed in accordance with any statutory provisions and in accordance with these guidelines.

1.1 Packing of DAAs

The packing 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/technicians, and the work subject 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 clean, tidy and orderly, and not accessible to the public. Adequate breaks are necessary owing to the mechanistic nature of the task.

The ability to review the patient's current medication regimen and medication history is essential, and pharmacists need to consider the stability and safety of medicines being packed in a DAA and identify those not suitable for packing in a DAA. The section *Crushing, dispersing or repackaging medicines* in the current edition of the *Australian Pharmaceutical Formulary and Handbook* should be referred to for guidance on the suitability of medicines to be packed into a DAA, and assigning of an expiry date to the DAA.

Tablets and capsules should be distributed into the compartments in such a way as to prevent physical incompatibilities between medicines, and the contamination of the medicines being packed as well as that of the local environment, so as not to pose any health or safety risks to the person doing the packing, other staff, patients and their carers (also refer to Guideline 1.5 *Packing oral cytotoxic and other hazardous medicines into DAAs*). Appropriate hygiene procedures

need to be followed prior to, during and following the packing process.

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

Pharmacists must ensure compliance with state and territory legislation in relation to the storage of, and access by staff to, medicines that are packed into DAAs.

When Schedule 8 poisons (Controlled Drugs) are included in a DAA, pharmacists must ensure that the storage of such medicines in the pharmacy is in accordance with any state or territory requirements. If the DAA containing Schedule 8 poisons is for a patient at a hospital or residential care facility, it must be packed in such a way as to enable storage at the facility that is in accordance with any state and territory requirements.

1.2 Labelling of DAAs

The label on the DAA should maximise adherence, promote usability and minimise error associated with administration of the patient's medicines. It should also support the patient or carer's understanding of the dosing regimen and include suitable information to minimise adverse effects.

The DAA label must include the particulars required under state and territory legislation, and include:

- the patient's name
- the name, address and telephone number of the pharmacy or pharmacy department from which the DAA was supplied
- the name, strength and dose form of each of the medicines in the DAA
- the directions for use for each of the medicines including frequency and dose
- any required cautionary and advisory labels for the medicines as outlined in the current edition of the *Australian Pharmaceutical Formulary and Handbook*
- the date of packing, applicable storage directions and the expiry date of the DAA, and
- the words 'Keep out of reach of children'.

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Pharmacists should only use DAA packs that can accommodate these labelling requirements.

Best practice is to include both the active ingredient (Australian approved name) and brand names on the label. When circumstances necessitate, such as space limitations, the active ingredient (Australian approved name) should be included. Where there is insufficient space for this, the brand name only can be used, provided this is in accordance with any state and territory requirements.

In the case where only one name is included on the DAA label, additional information should be provided to the patient and/or their carer(s) to ensure access to the active ingredient and brand name of all medicines packed into the DAA, for example through provision of a current medication list at every change of medication or brand of medication.

The DAA label and medication list, if provided, should be clearly and legibly printed in plain English. Where space permits, other languages that are accurate translations of the English may be used in addition to English. Pharmacists should ensure that the DAA label used is durable and legible for the expected duration of use of the container.

In appropriate circumstances, a photograph of the patient may be attached to the DAA. Cautionary and advisory labels can be attached for the corresponding medication, either directly to the DAA or on a separate sheet such as the medication list (where provided).

Pharmacists should give consideration to whether additional information such as patient allergies, medications taken by the patient that are not included in the DAA, or recent changes to the patient's medication regimen, should be included on the DAA label or provided as ancillary information. A product identification option to assist nurses and carers is recommended, such as a coloured picture or description of each medicine in the DAA.

1.3 Checking of DAAs

A packed DAA must be checked by a pharmacist before it is supplied to a patient, to ensure that it has been packed accurately and is in accordance with the patient's current medication regimen. Pharmacists should exercise

vigilance when undertaking this important task, which is as important as the check of any individually dispensed medicine. Sufficient time without interruption should be dedicated to undertaking this important task.

1.4 Records of DAA packing

In addition to meeting state and territory legislative requirements for the record keeping of dispensed medicines, a record of each packing into a DAA should be made under the patient's name with:

- each medicine's name, form, strength and dose
- the date of packing
- the initials of the person who packed it and those of the pharmacist who checked it, and if the packing is done by a third party the initials of the supply pharmacist (refer to Guideline 1.7 *Packing by a third-party*)
- the date of supply of the DAA to the patient or their agent, and
- the quantity of a patient's medication that remains after packing.

The packing record should be retained for at least six months.

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

1.5 Packing oral cytotoxic and other hazardous medicines into DAAs

Oral cytotoxic and other hazardous medicines should only be packed into a DAA if there is evidence that the benefit of improved patient adherence from using a DAA outweighs the risk of exposure to the medicine when taking or administering it from a DAA, or when packing the DAA. This risk assessment should include discussion with the patient and/or their carer to assess their ability to administer the medication correctly and safely from the chosen container, in accordance with the prescriber's instructions. Warning statements included on the manufacturer's packaging, such as a warning about the risk of teratogenicity if a medicine is used in pregnancy, should be included on the DAA label if a decision is made to repackage that medicine into a DAA.

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Given the narrow therapeutic index of cytotoxic medicines and the risk of death from incorrect dosing, extra vigilance must be exercised when dispensing and packing these medicines into DAAs. For these reasons, the Board advises pharmacists that:

- other non-cytotoxic medicines for a patient must not be placed in the same DAA, and
- the DAA containing the cytotoxic medicine must be labelled with a cytotoxic warning label in addition to all other information required when labelling a DAA.

The packing of cytotoxic medicines into DAAs should be undertaken by a pharmacist, or if circumstances require, by a suitably trained pharmacy student, intern or dispensary assistant after which the DAA must be checked by a pharmacist.

The packing of cytotoxic and other hazardous medicines into DAAs should be undertaken in a suitable environment using suitable equipment, systems and techniques to minimise direct exposure to these medicines, as outlined in the practice standards. Pharmacists should also refer to the section *Crushing, dispersing or repackaging medicines* in the current edition of the *Australian Pharmaceutical Formulary and Handbook* for further guidance.

1.6 Automated and semi-automated dose packaging systems

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

Pharmacists who use automated or semi-automated dose packaging machines must ensure:

- there is a cleaning and maintenance protocol that is adhered to
- testing is carried out at the start of each day and at any other time, as may be operationally required
- any person using the machine has received initial training and demonstrated competency in its use, and receives 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 degrees Celsius

- there is a written procedure describing the use of the machines, including maintenance and error records, and
- there is a written quality assurance program that includes the refilling of bulk canisters.

Any requirements of the relevant state or territory pharmacy premises registering authority must also be met.

1.7 Packing by a third-party

When in accordance with state and territory legislative requirements, a pharmacist may engage the services of a third party to pack a DAA on their behalf (e.g. a Therapeutic Goods Administration (TGA) licensed facility or another pharmacy).

The supply pharmacist (who supplies the DAA to the patient or their agent):

- must ensure that the patient's right to privacy is understood, the patient or agent has consented if a third party is to be involved in the packing of the DAA, and a record of the consent is kept
- is responsible for ensuring the packing pharmacist has accurate details of the medicines to be packed
- must make an assessment of the measures, techniques and technology used by the packing pharmacist at the third party packing facility to check packed DAAs for accuracy, to determine whether additional checking of a DAA is required prior to its supply to a patient or their agent, and
- is responsible for the quality use of medicines support for the patient, including provision of accompanying medicines information to the patient or their agent.

The packing pharmacist at the third party packing facility is responsible for ensuring DAAs are prepared in a timely and accurate manner according to the patient's current medication regimen.

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The direct supply of the DAA to the patient or their agent from the third-party packing facility is unlawful and must not take place, even if pharmacists are employed at that facility. It is the responsibility of the supply pharmacist to make the supply of the DAA to the patient or their agent.

A packing pharmacist who uses an automated or semi-automated dose packaging system on behalf of a supply pharmacist may need licensing by the Therapeutic Goods Administration in jurisdictions that have laws to complement the *Therapeutic Goods Act 1989* (Cth).

2 Staged supply

Staged supply is the process by which pharmacists supply medicine to a patient in periodic instalments of less than the originally prescribed quantity, at agreed time intervals. The balance of the medicine is held by the pharmacy to fulfil subsequent instalments. This service can be initiated by the pharmacist, the prescriber, the patient or their agent, or another health professional involved in the care of the patient¹.

Staged supply should be in accordance with any state and territory regulations.

Guideline

The staged supply of medicines, including methadone and buprenorphine, should be provided in accordance with the prescriber's request (when initiated by a prescriber), state or territory regulations and guidelines issued by relevant authorities.

For the staged supply of medicines, which may include the supply of Schedule 8 poisons (Controlled Drugs), the storage of the medicines and the recording of the staged supply must be in accordance with any state or territory requirements.

Consideration of the individual patient circumstances and needs is required to achieve an effective staged supply arrangement. The patient's consent should be obtained, including a written agreement between the

pharmacist and the patient. The dispensed medicine should be stored and administered periodically with consideration of the patient's privacy. Appropriate records of the periodic supply should be maintained and reviewed to ensure that the arrangement remains effective and in accordance with the agreement. Where necessary, further contact with the patient, their agent, the prescriber and/or another health professional involved in the care of the patient, may be required to achieve compliance.

The patient and the prescriber should be informed of the proposed staged supply arrangement, including pricing for the service, so that an informed decision about the service can be made.

Definitions

A **co-regulatory jurisdiction** means a participating jurisdiction in which the National Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8. Queensland and New South Wales are co-regulatory jurisdictions.

Dose administration aids (DAAs) are defined in a number of documents. For the purpose of these guidelines, a DAA is defined as a device or packaging system for organising doses of medicines according to the time of administration, which assists medication management for a patient.

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

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

¹ Derived from Pharmaceutical Society of Australia 2015, *Staged supply*, Pharmaceutical Society of Australia, viewed 18 June 2015, www.psa.org.au/supporting-practice/5cpa/ppi-staged-supply

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References

Pharmacy Board of Australia *Guidelines for dispensing of medicines*

Review

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These guidelines will be reviewed at least every five years.

From 7 December 2015, these guidelines replace the Pharmacy Board of Australia *Guidelines on specialised supply arrangements* published 12 August 2010.