

Dose Administration Aids Service

Pharmaceutical Society of Australia
July 2007



**Pharmaceutical
Society of Australia**

Guidelines and standards for pharmacists

Table of Contents

Dose Administration Aids Service – Guidelines for pharmacists	3
1. About the guidelines	3
1.1 Background	3
1.2 Purpose of the guidelines	3
1.3 Scope of the guidelines	3
2. Introduction	4
2.1 Terminology	4
2.2 Overview	4
3. Establishing a DAA service	5
3.1 Considerations prior to establishing a DAA service	5
3.2 Selecting a DAA system	5
3.3 DAA preparation area	6
3.4 Staff responsibilities	6
3.5 Training of staff	7
3.6 Policies and procedures	7
4. Assessment of consumers for whom a DAA service is being considered	8
4.1 Making a formal assessment	8
4.2 Concluding the assessment	8
4.3 Communication with GPs	9
4.4 Communication with consumers	9
4.5 Privacy considerations	10
5. Process for preparing DAA	10
5.1 Prior to packing a DAA	10
5.2 Packing a DAA	10
5.3 Record keeping for DAA	10
5.4 Labelling of a DAA	10
5.5 Changes to a DAA	11
5.6 Third parties	11
6. Medicines in DAA	11
6.1 Medicines stability	11
6.2 Cytotoxics	12
6.3 Controlled Drugs	12
6.4 Medicines ordered on an 'as required' basis	12
6.5 Maximum number of medicines per pack	12
6.6 Sealing DAA packs	13
6.7 Child resistant packaging	13
6.8 Time which medicines can be left in DAA	13
6.9 Reuse of medicines	13
7. Monitoring	13
7.1 The monitoring process	13
7.2 Non-adherence or decreasing ability to cope with DAA	14
8. Quality assurance	14
Appendix 1: DAA service funded under the Fourth Community Pharmacy Agreement	15
Appendix 2: Assessment of consumer non-adherence when considering a DAA	16
Appendix 3: Discussion guide and sample agreement for a DAA Service	17
Appendix 4: Record of packing dispensed medicines into DAA	19
Appendix 5: Examples of medicines which should not be packed in DAA	20
Dose Administration Aids Service – Standards for pharmacists	21

The development and production of this document was funded by the Australian Government through the Third and Fourth Community Pharmacy Agreements.

The Pharmaceutical Society of Australia gratefully acknowledges the contribution of various stakeholders to this project and in particular, the following individuals:

Pharmacist consultant

Michael Ryan (Director, PharmConsult)

Expert Pharmacists

Karalyn Huxhagen

John Jackson

Grant Kardachi

Dr Julie Stokes

Dimitra Tsucalas

© Pharmaceutical Society of Australia 2007

ISBN: 978-0-908185-91-7

Disclaimer

The Pharmaceutical Society of Australia has made every effort to ensure that, at the date of publication, this document is free from errors and that advice and information drawn upon have been provided in good faith. Neither the Pharmaceutical Society of Australia nor any person associated with the preparation of this document accepts liability for any loss which a user of this document may suffer as a result of reliance on the document and in particular for:

- Use of the guidelines and standards for a purpose for which they were not intended;
- Any errors or omissions in the guidelines and standards;
- Any inaccuracy in the information or data on which the guidelines and standards are based or which are contained in them; or
- Any interpretations or opinions stated in, or which may be inferred from, the guidelines and standards.

Endorsed by PSA Board July 2007

Dose Administration Aids Service – Guidelines

1. About the guidelines

1.1 Background

The review of PSA's Dose Administration Aids (DAA) Guidelines (endorsed in 1999) was prompted by a number of developments relating to the provision of a DAA service including:

- the release of the reports of the Effectiveness and Cost Effectiveness of Dose Administration Aids projects conducted under the Third Community Pharmacy Agreement;^{2,3}
- changes to practice, care arrangements and legislation;
- the introduction of a number of new DAA systems; and
- the announcement of a DAA program as part of the Fourth Community Pharmacy Agreement.

These guidelines draw on the research, findings and consultations of the Effectiveness and Cost Effectiveness of Dose Administration Aids projects, the experience of the pharmacy registering authorities throughout Australia, the input of expert pharmacists, DAA system vendors and others and were developed after consultation with representatives from the pharmacy sector, government and consumers.

1.2 Purpose of the guidelines

The purpose of these guidelines is to provide a framework linked to processes and practical advice to enable pharmacists to implement a DAA service for suitable consumers using systems that uphold the principles of the Quality Use of Medicines (QUM) i.e. of:

- selecting management options wisely;
- choosing suitable medicines if a medicine is considered necessary; and
- using medicines safely and effectively.

The guidelines have been developed to assist pharmacists to maximise safety and quality in this aspect of medicines use.

It is essential to review the professional practice standard on Dose Administration Aids Service⁴ which can be found at the end of this publication. The guidelines are designed to assist pharmacists exercise their professional judgment in meeting the standard. The standard relates to the systems pharmacists should have in place for the delivery of a DAA service and provides a benchmark against which performance can be assessed.

Pharmacists are also reminded that the DAA Service standard must be applied in the context of other relevant professional practice standards which may include *Fundamental Pharmacy Practice*,⁵ *Dispensing*,⁶ *Counselling*,⁷ *Services to Residential Care Facilities*,⁸ and *Organisation of Pharmacy Practice*.⁹

1.3 Scope of the guidelines

This document provides guidance on issues that need to be considered and steps to take when establishing a DAA service and the process to be followed in providing, and monitoring the outcomes of the DAA service.

Although the focus of the guidelines is on DAA which require the manual packing of medicines, key principles are applicable to all types of DAA including automated and computerised dose packing systems (ADPS). It is acknowledged that pharmacists may receive requests from consumers to pack dosette-type tablet organisers (or similar devices). These guidelines do not specifically cover the packing of those containers which do not provide the security or controlled storage conditions of 'closed' DAA. However, pharmacists are encouraged to follow these guidelines where appropriate since key aspects such as patient assessment and monitoring would also apply to tablet organising devices.

The guidelines are designed to be applicable to all practice settings in which pharmacists may work and to all consumers in whichever setting they reside throughout Australia.

It is assumed that pharmacists will apply professional judgment in managing risks in each of the steps involved in the provision of a DAA service particularly in aspects where conclusive data is limited such as data on stability of medicines when packed in DAA. Pharmacists will need to frequently make risk-benefit assessments based on the best available information. These decisions should be recorded together with the rationale on which the decision was based.

1. In these guidelines, for simplicity and clarity, the abbreviation "DAA" is used for both the singular and plural forms of 'dose administration aid(s)'. In the Standard (at the end of this publication) which was developed in 2006, readers will find "DAA" and "DAAs" used for the singular and plural forms, respectively.

2. Ientile C, Stokes JA, Roberts MS. Effectiveness and cost effectiveness of dose administration aids. Final Report. Quality Medication Care Pty Ltd and the Therapeutics Research Unit, University of Queensland. 5 November 2004. Available at: www.guild.org.au/uploadedfiles/Research_and_Development_Grants_Program/Projects/2002-519_fr.pdf

3. Stokes JA, Ientile C, Roberts MS. Effectiveness and cost effectiveness of dose administration aids. Phase 3 Final Report. Quality Medication Care Pty Ltd and the Therapeutics Research Unit, University of Queensland. 11 May 2006. Available at: www.guild.org.au/uploadedfiles/Research_and_Development_Grants_Program/Projects/2004-536.pdf

4. Pharmaceutical Society of Australia. Professional Practice Standards. Version 3, 2006. pp. 65–70. Available at: www.psa.org.au

5. *ibid.*, pp. 13–21.

6. *ibid.*, pp. 43–9.

7. *ibid.*, pp. 59–63.

8. *ibid.*, pp. 127–35.

9. *ibid.*, pp. 137–42.

Guidelines and standards for pharmacists

Although the general principles contained in this document may be used by other health professionals who may pack DAA, these guidelines are intended to apply to the packing of DAA by, or under the supervision of, a pharmacist.

Details of legislative requirements are not addressed in these guidelines. It is assumed that pharmacists will comply with relevant Commonwealth legislation (including the *National Health Act 1953* and its requirements in regard to the Pharmaceutical Benefits Scheme) and State/Territory legislation in the provision of this service.

Where the service is provided under a particular service framework operating under any specific funding arrangements, pharmacists are responsible for meeting any specific requirements under the relevant program guidelines. Pharmacists intending to deliver DAA services under funding provided by third parties must ensure that the program requirements implemented by the third party do not contravene any of the requirements of professional practice standards. If the provision of a DAA service is to be funded or subsidised by arrangements other than payment by the consumer, the pharmacist is responsible for meeting the relevant requirements stipulated by the funder / payer. Due care must be taken as such requirements may specify, for example, the type of DAA to be supplied, eligibility criteria for the consumer, and documentation required for payment and for audit purposes.

Appendix 1 provides some information relating to the DAA service funded under the Fourth Community Pharmacy Agreement.

2. Introduction

2.1 Terminology

For the purposes of these guidelines, a **dose administration aid** (DAA) is a tamper-evident, adherence device developed to assist medication management for a consumer by having medicines divided into individual doses and arranged according to the dose schedule throughout the day. It can be either a unit-dose pack (one single type of medicine per compartment) or a multi-dose pack (different types of medicines per compartment).¹⁰

The term **medicine** includes prescription, non-prescription and complementary medicines.

A **DAA Profile** is a document prepared by a pharmacist which sets out information relating to the consumer (e.g. age, allergies, co-morbidities) and their current medication regimen.¹¹ It also documents:¹²

- a) the consumer's behaviour and preferences related to taking medicines;
- b) any physical constraints the consumer may have that may affect their medication management abilities (e.g. impaired vision);
- c) the general practitioner's (GP's) specific requests (if any) in regard to the way the consumer should take a specific medicine;
- d) the type of DAA and packing interval;
- e) verification that the prescribed medicines have been checked as suitable for packing in a DAA;
- f) risk-benefit assessments and decisions made by the pharmacist and the rationale upon which the decisions were made;
- g) the date the DAA Profile was compiled or updated/reviewed;
- h) a record of the changes which have been made, the name of the person who requested the change, and the initials of the pharmacist who made the change; and
- i) an assessment of the consumer's progress in managing their medicines.

In this document, the term **consumer** can mean a potential user of health products and services, or a person in receipt of medical and/or therapeutic services or advice.¹³ The term is used in an inclusive sense to cover 'consumer', 'consumer and carer' or 'consumer or carer'. In this context, **carer** means an individual who contributes to the care of another person either because they have been formally engaged to do so, or because of their personal or family relationship to that person.¹⁴

2.2 Overview

The supply of medicines in a DAA (as part of a medicines management system) has potential advantages for consumers that include:

- a) improving adherence and medication management;
- b) decreasing the incidence of adverse events from medication mismanagement;
- c) decreasing hospitalisation due to medicine misuse; and
- d) possible cost savings through prevention of hoarding of medicines.

10. Australian Government Department of Health and Ageing. Professional Programs and Services Advisory Committee. Dose administration aids program questions and answers. April 2007.

11. Stowasser DA, Allinson YM, O'Leary KM. Understanding the medicines management pathway. *J Pharm Pract Res* 2004; 34:293-6.

12. Stokes, Lentile, Roberts, op. cit., p. 69.

13. Pharmaceutical Society of Australia. Competency standards for pharmacists in Australia 2003. November 2003.

14. *ibid.*

Guidelines and standards for pharmacists

A DAA service must be considered a part of the medication management pathway as it includes key components such as dispensing and counselling. A DAA supports safer care at both the distribution and administration steps of the pathway.¹⁵ A DAA is a device that should be used in a co-ordinated approach to medication management.¹⁶ It is not a complete medication management system and other measures or strategies need to be employed to ensure the appropriate and timely use of medicines not included in the DAA. Strategies such as patient assessment and patient education are an integral part of a DAA service that can improve adherence and medicine management by providing an opportunity for directive guidance.¹⁷

From a QUM perspective and in assisting consumers who have adherence issues with their medicines, a DAA service has close linkages with other professional services provided by pharmacists such as the provision of Consumer Medicine Information (CMI),¹⁸ Home Medicines Reviews (HMR),¹⁹ Residential Medication Management Reviews (RMMR)²⁰ and the provision of patient medication profiles.²¹

3. Establishing a DAA service

3.1 Considerations prior to establishing a DAA service

To establish a DAA Service, a pharmacist should:

- a) understand the full extent of what is required in the provision of a DAA service including consumer expectations;
- b) determine if there are consumers for whom the provision of a DAA service will provide benefits over existing methods of supplying medicines;
- c) estimate the number and type of consumers for whom the DAA service will be provided in order to appropriately plan for the packing facilities and requirements;
- d) anticipate as far as practicable the demand a DAA service will have on pharmacy resources for the expected number of DAA likely to be supplied;
- e) ensure adequate time and resources can be allocated for packing DAA;

- f) ensure that adequate time and resources can be allocated for ongoing supervision of the DAA area including the review of documentation such as creating, reviewing and maintaining DAA Profiles;
- g) be able to provide a DAA computer system if required, and the necessary training for staff to operate the system effectively and reliably; and
- h) be able to have documented processes and procedures to provide direction to staff (see section 3.6).

3.2 Selecting a DAA system

A DAA must be capable of providing the correct medicine, at the correct dose and time, in a safe and hygienic manner. Ideally, a DAA must be designed to:

- a) be easy to use with clear and complete labelling and instructions as to when medicines should be taken and appropriate for each consumer;
- b) enable medicines to be set out in a manner appropriate for the prescribed dosing schedule;
- c) secure the medication from moisture and contamination;
- d) be easily accessed by consumers;
- e) limit ready access by children;
- f) provide labelling which will identify all individual medicines packed in the DAA;
- g) carry information for the consumer to administer medicines not packed in the DAA if possible;
- h) provide a structure capable of maintaining the integrity of medicine (during transport, storage, regular distribution and the potential for accidents such as being dropped); and
- i) support a mechanism, or a system, that can show evidence of tampering.

A DAA may be in the form of:

- a) unit dose packing [where the dose (single or multiple units) of a single type of medicine is packed in each compartment, blister or pouch pack]; or
- b) multi-dose packing (where doses of more than one medicine can be packed in one compartment, blister or pouch pack).

The range and type of DAA available in Australia has broadened with the availability of automated and computerised dose packing systems (ADPS). As the name suggests, with ADPS the execution of tasks such as medicines counting, packing into 'pouch packs', labelling and electronic documentation are computerised and automated. The use of ADPS may be subject to certain requirements under therapeutic goods legislation such as the *Code of Good Manufacturing Practice* and licensing by

15. Stowasser, Allinson, O'Leary, op. cit.

16. Australian Pharmaceutical Advisory Council. Guiding principles for medication management in the community. Guiding principle 3 – dose administration aids. June 2006. Available at: www.health.gov.au/internet/wcms/publishing.nsf/content/apac-publications-guiding

17. Gupchup GV, Wolfgang AP, Thomas J. Development of a scale to measure directive guidance by pharmacists. *Ann Pharmacother* 1996; 30:1369-75.

18. Pharmaceutical Society of Australia. Consumer Medicine Information and the pharmacist. January 2007.

19. Pharmaceutical Society of Australia, Professional Practice Standards, pp. 35–42.

20. Pharmaceutical Society of Australia. Guidelines and Standards for the Collaborative and Pharmacist Residential Medication Management Review (RMMR) Program and Associated Quality Use of Medicines (QUM) Services. 2006.

21. Pharmaceutical Society of Australia. Guidelines and Standards for the provision of a medication profile. [Under development.]

Guidelines and standards for pharmacists

the Therapeutic Goods Administration (TGA).²² Pharmacists should seek advice from the suppliers of ADPS on the medicines generally not recommended to be packed in pouch packs.

Pharmacists using this automated technology to pack medicines for consumers must ensure:

- a) the right of the consumer to privacy is understood and that if a third party is involved in the packing of the DAA, consent is obtained from the consumer for this involvement;
- b) the ADPS is operated in a clean environment, and if in a pharmacy, away from the dispensing computer and bench area of the dispensary;
- c) that all staff involved in using ADPS machinery receive appropriate initial and ongoing training and that such training is documented;
- d) the labelling of the container in which the pouch packs are placed, complies with all labelling requirements of relevant legislation and pharmacy registering authority guidelines;
- e) that records maintained at or accessible by the pharmacy include the batch number, expiry date, packing date, and the initials of the person responsible for packing the DAA. If a dispensary assistant performs the packing the record must also include the initials of the pharmacist responsible;
- f) there is a documented cleaning and maintenance protocol that is strictly followed;
- g) there is a regular maintenance schedule in place to calibrate the software and hardware components of the ADPS;
- h) that quality control processes which check data entry, medicines loaded into the ADPS, and final product are in place and that there is evidence these are followed; and
- i) there is a process for documenting and resolving irregularities which may be detected during the quality control processes.

While a thorough understanding of the mechanical systems involved in ADPS machines may be outside the role of pharmacists, knowledge of the system should at least include how to:

- a) operate the ADPS to produce the desired outcome;
- b) integrate system with a manual backup;
- c) recognise when a system failure occurs or is imminent;
- d) protect consumer safety when failures occur; and
- e) have failures corrected expeditiously.

3.3 DAA preparation area

A pharmacist should:

- a) dedicate an area in the pharmacy (or another area not in the pharmacy which meets pharmacy registering authority requirements) for the preparation of DAA which has adequate space for the installation and operation of a DAA system and is clean, free from interruption, and allows a methodical approach to the packing of DAA. This area must have sufficient capacity to allow the orderly storage of DAA products and materials, as well as the individual medicines dispensed prior to transferring them to the area where the DAA will be packed;
- b) ensure that the DAA area and working conditions for staff meet applicable occupational health and safety requirements;
- c) provide hand washing facilities in the DAA preparation area to enable staff to maintain hygiene prior to, throughout and at the completion of, duties involving DAA; and
- d) ensure that procedures for the assembly of a DAA are designed to minimise the possibility of cross contamination between DAA. This is particularly relevant where medications for a large number of different consumers are being prepared at the same time.

3.4 Staff responsibilities

A pharmacist should employ and train an appropriate number of pharmacists and dispensary assistants in order to provide a service which meets legal and professional requirements. Adequate provision must also be made for staff time required to process and check DAA as well as liaise with consumers and prescribers.

In addition to responsibilities associated with dispensing, a pharmacist must:

- a) ensure the accuracy of the DAA Profile to be used in preparing a DAA;
- b) make professional judgements about the medicines to be packed in a DAA and any related actions to be taken;
- c) supervise the preparation of DAA;
- d) check and sign the completed DAA before issue; and
- e) ensure that appropriate records are kept and that a quality assurance program is in place.

22. Pharmacy Board of Victoria. Guidelines for good pharmaceutical practice 2004 (amended). G480A, p. 36.

23. Barker KN, Felkey BG, Flynn EA, Carper JL. White paper on automation in pharmacy. Consult Pharm 1998; 13(3):256-93.

Guidelines and standards for pharmacists

A pharmacy student, a pharmacy pre-registration graduate, pharmacy technician or a dispensary assistant may assist the pharmacist by:

- a) setting out medicines in DAA;
- b) preparing labels and typed instructions;
- c) attaching dispensing, cautionary and advisory labels to DAA;
- d) carrying out appropriate record-keeping; and
- e) undertaking other non-judgemental tasks as allowed under pharmacy registering authority guidelines.

3.5 Training of staff

Staff involved in the packing of DAA should have the necessary training and practical experience.

Pharmacists must have an understanding of the legal and professional requirements related to DAA, and training in the provision of a DAA service to meet these requirements.

Dispensary staff should have a general understanding of the overall DAA service provided by the pharmacy and the policies and procedures for the service. Staff should have a sound understanding of those policies and procedures with which they are directly involved.

Training of dispensary staff in assisting in the provision of a DAA service should include instruction and supervised practice in the following areas:

- a) understanding and applying personal hygiene and dress code;
- b) occupational health and safety requirements;
- c) appropriate storage of dispensed original packs of medicines, materials used in the preparation of a DAA, and completed DAA;
- d) understanding and handling of the medicines which require specific storage conditions within DAA;
- e) use of all equipment involved in preparing DAA including heat sealing equipment (unless cold press system is in use), tweezers, gloves;
- f) specific hygiene requirements with respect to handling medicines to be packed in a DAA;
- g) record keeping required for a DAA service;
- h) setting out medicines in DAA;
- i) sealing, labelling and storage of DAA;
- j) handling of returned DAA;
- k) quarantining and destruction of returned unused medicines;
- l) any support activities such as interactions with GPs or direct dealings with consumers; and
- m) quality control procedures and other relevant risk management plans associated with DAA.

The provision of training and the assessment of the results of training through observed practice, should be recorded e.g. in a personnel record in the Quality Care Pharmacy Program, or in a DAA manual.

3.6 Policies and procedures

A policies and procedures manual for the DAA service developed by individual pharmacies should cover all aspects of the service and explicitly describe the responsibilities of staff involved in the DAA service. It should also address:

- a) effective communication with all relevant parties;
- b) training of staff; and
- c) a quality assurance process.

Effective documentation is essential to maximise safety, quality and efficiency. A procedure manual and relevant forms and templates must be available to all regular and locum staff. Staff should record that they have read, and are familiar with, the policies and procedures. A procedure manual should include all procedures with references to and location of all required documentation. The procedures should be systematically reviewed and updated, as required, and at regular intervals. The review should be documented by annotating the date of review on the manual.

Pharmacists providing a DAA service should have documented processes and procedures to provide direction to all those involved in the service for issues such as:

- a) formal assessment of consumers considering or being considered for a DAA service;
- b) creating and maintaining a DAA Profile;
- c) handling the DAA devices and consumables (e.g. sealing and cleaning);
- d) the process for preparing DAA;
- e) packing, delivering and documenting medicines with a high risk of adverse incident (e.g. cytotoxic drugs, Controlled Drugs, and anticoagulation drugs);
- f) supplying 'as required' ('prn') and short-term medicines;
- g) supplying DAA to remote areas or consumers in isolated areas (if required);
- h) where a computer system is used, using the computer software to add new consumers, change consumer details, and print labels, foils, header cards and necessary signing sheets;
- i) maintaining a written record of all communication regarding medicine changes for consumers receiving DAA services since the accuracy of the DAA pack is largely dependent on the currency of the DAA Profile;
- j) changing DAA Profiles including confirmation of changes, and who authorised changes;
- k) notifying consumers when ordered medicines are unavailable and taking appropriate steps including making contact with the prescriber;

- l) managing the return of unused medicines to the pharmacy;
- m) monitoring DAA use; and
- n) reporting DAA incidents and the recording of these.

4. Assessment of consumers for whom a DAA service is being considered

Where the use of a DAA is being considered for a consumer intending to manage their own medicines, the consumer's needs and their ability to manage a DAA should be formally assessed, prior to the initiation of the DAA service. The role of a carer who may assist the consumer also needs to be considered. This assessment of the likelihood of a DAA assisting consumers with medicine adherence and related issues needs to consider the risk of medication misadventure through non-adherence, the potential for misuse of a DAA or the potential for decline in the consumer's knowledge of their medicines regimen.

In identifying consumers who are likely to benefit from a DAA, there is no single set of criteria which can cover all potential scenarios or consumer needs. Some consumers on one regular medicine may benefit from the use of a DAA, while others taking a large number of medicines may have no problems managing their medicines. Examples of situations where consumers may benefit from a DAA include consumers:²⁴

- a) taking five or more medicines daily (including non-prescription medicines);
- b) with a medical history suggesting problems managing medicines (e.g. prior hospitalisation due to poor adherence);
- c) with a complex regimen of medicines; or
- d) with signs of cognitive or physical impairment which may affect their ability to effectively manage medicines.

4.1 Making a formal assessment²⁵

When considering the provision of a DAA service to a consumer, a pharmacist should:

- a) assess each consumer for their likelihood to benefit from, and ability to use, a DAA (see Appendix 2) including abilities, behaviours and attitudes to taking medicines that may impact on DAA use and conditions which may limit the consumer's capacity to safely and effectively use the DAA (e.g. visual impairment, diminished dexterity due to arthritis); and

- b) discuss with and ascertain the consumer's understanding of a DAA service, for example, explaining DAA functionality, the packing procedure and the procedure for authorising dosage changes, and the likely benefits and practicalities of using a DAA. The pharmacist should discuss these issues as part of an assessment including actually checking that the consumer can effectively use the proposed DAA, using a sample pack (in a similar way to demonstrating inhaler technique).

A review of the consumer's current medicines, medicine management and medicines knowledge is integral to the assessment process. A needs and risk assessment should take into account issues such as the number of medicines a consumer takes each day (including non-prescription and complementary medicines), and the complexity of the medicines regimen. An HMR may be a valuable way to do this assessment. Other factors which should be taken into account include:

- a) the level of available social support e.g. whether a carer is regularly available to supervise or assist with medicines taking;
- b) the number of medicines prescribed for the consumer and the number which can be safely and securely packed in the DAA;
- c) the number of medicines which are not suitable for packing in a DAA (since a large number of these may increase the complexity of medicines management with a DAA);
- d) the consumer's knowledge of the medicines they are taking; and
- e) the existence of another health professional's written assessment of the consumer.

4.2 Concluding the assessment

After compiling the required information, the pharmacist can make a decision as to the suitability of a DAA for a consumer and formulate a plan to manage potential consumer risks. Ideally, this plan is included in the DAA Profile. At the conclusion of the assessment and before initiation of the service, the pharmacist should:

- a) ensure the consumer understands the necessary elements of the DAA service to be provided, for example, explaining how to use the DAA, authorising changes to packed medicines, and if discussed previously, reinforcing the likely benefits and practicalities of using a DAA (see section 4.4);
- b) formalise the service to be delivered (including expectations and obligations) in a written agreement between the consumer and the pharmacist (see section 4.4, and Appendix 3 for a proforma which can be adapted for this purpose). A clear understanding of expectations and obligations can avert future problems;

24. Stuck AE, Tamai IY. Medication management in the home. *Clin Geriatr Med* 1991; 7:733–48.

25. Svarstad B, Chewning B, Sleath B, et al. The brief medication questionnaire: a tool for screening patient adherence and barriers to adherence. *Patient Educ Couns* 1999; 37:113–24.

Guidelines and standards for pharmacists

- c) produce a DAA Profile for packing which shows the medicines' regimen and reflects the consumer's and the GP's preferences, any constraints or conditions the consumer may have (e.g. impaired vision) which would impact on the use of a DAA, the current medicines, the type of DAA and packing interval, the suitability of each medicine intended to be packed in a DAA, and the medicines which are not packed in the DAA including the strategies to support adherence with non-packed medicines;
- d) have the DAA Profile confirmed by the consumer with a copy provided to their GP for information.

4.3 Communication with GPs

For the provision of a safe, effective, and efficient DAA service, it is considered essential to have effective collaboration of, and communication between, relevant members of the health care team which may include the GP, the pharmacist, the consumer, the carer, the community nurse, hospital or residential aged care facility staff.²⁶ Incomplete or inefficient communication can lead to rework and delays for the pharmacy, but also compromises the achievement of optimal therapeutic outcomes and exposes consumers to potential risks.

Pharmacists and GPs should communicate (regularly and where appropriate) in relation to:

- a) the initiation of a DAA for a consumer;
- b) the maintenance of an up-to-date DAA Profile;
- c) the provision of prescriptions;
- d) the mechanism for communicating changes and urgency with which changes need to be implemented;
- e) concerns with the consumer's adherence as evidenced, for example, by missed doses (which may be indicative of other issues that need to be addressed by the GP);
- f) any difficulties the consumer may be experiencing in the use of a DAA; and
- g) any other options available to eliminate or reduce the difficulties associated with medicines taking.

4.4 Communication with consumers

Once an assessment has been made that the consumer would benefit from a DAA and provision of a DAA service has been agreed, the pharmacist should:

- a) inform the consumer of the DAA provision process, including where relevant any service requirements related to funded models;

- b) advise the consumer of fees charged for DAA provision other than the cost of medicines;
- c) advise the consumer of associated services with DAA provision such as prescription management and delivery;
- d) discuss and agree with the consumer on a time and procedure for collection of the packed DAA;
- e) arrange for the storage of dispensed medicines in the pharmacy;
- f) discuss the type of DAA available that will best meet the consumer's needs;
- g) seek / confirm the consumer's consent for involvement in a DAA service and for release of data to approved third parties where appropriate, involvement of other health professionals including consent for the pharmacist to contact the consumer's GP as required to ensure the DAA Profile is up-to-date or to advise of prescription requirements and to discuss medicine management or the sharing of medicine regimen information with hospitals or other facilities should the need arise;
- h) in addition to the GP communicating with the pharmacy, request the consumer to advise the pharmacy of any medicine changes;
- i) confirm the consumer's consent through the consumer signing a completed 'service agreement' (see Appendix 3 as a template that can be used for this purpose);
- j) in the case of Aboriginal and Torres Strait Islander people in remote, urban or other areas, it may be more appropriate to request a signed copy of a current medication regimen from the Aboriginal Medical Service;
- k) discuss with the consumer their preferences for when to take medicines if this is not consistent with the approved product information;
- l) discuss medicines which cannot be packed in a DAA (e.g. non-solid dose forms, 'prn' medicines) and provide advice on the management of these (e.g. provision of a medicines list);
- m) counsel the consumer on appropriate storage conditions (i.e. protection from heat, moisture and light) and on being vigilant in monitoring the DAA and its contents to ensure the integrity of the medicines is maintained throughout the dosage period;
- n) counsel the consumer appropriately (in accordance with guidelines) on issues arising from brand substitution in order to minimise confusion;²⁷
- o) advise the consumer to inform the pharmacist of any difficulty (e.g. physical, visual or other) in using the DAA or adhering to the medicine regimen;

26. Stokes, Ientile, Roberts, op. cit., p. 262.

27. Pharmaceutical Society of Australia. Guidelines for pharmacists on PBS brand substitution. July 2004.

Guidelines and standards for pharmacists

- p) advise the consumer to inform the pharmacist of any adverse effects or difficulties in taking the medicine (e.g. difficulty in swallowing);
- q) advise the consumer that the pharmacist may wish to have regular discussions (e.g. when the consumer returns the finished DAA to the pharmacy) about how they are managing with their medicines (this is an opportunity to also ascertain the reasons for 'non-taking' of medicines remaining in a returned DAA); and
- r) advise the consumer of the need for periodic reassessment and gain the consumer's agreement for this.

The use of a DAA by a consumer should not limit their access to CMI leaflets. Consumers in the private home and institutional setting (either directly or through their carers) should be supplied with CMI either on initial DAA provision or with significant medicine or regimen changes.

Regular counselling of consumers about their medicines and DAA use is essential to ensure the safe and effective use of their medicines and to minimise the risk of consumers losing their DAA-use skills or their knowledge of their medicine regimen.²⁸

4.5 Privacy considerations

The rights of consumers to privacy and confidentiality must be respected. Pharmacists must meet the relevant standard (criterion 1 of the *Fundamental Pharmacy Practice* standard)²⁹ in the provision of a DAA service.

5. Process for preparing DAA

5.1 Prior to packing a DAA

- a) The DAA area must be a dedicated area for DAA activities to minimise the chances of interruption and errors. All equipment and medicines required to pack a DAA must be easily accessible. A DAA should be packed for one consumer at a time. Where multiple staff are packing for different consumers at the same time, procedures should be designed to minimise the possibility of cross contamination between DAA.
- b) Following the supply of the original prescription or in the case of ADPS the preparation of the packing profile, the packing of a DAA must take place under the direct supervision of, and be checked by, a pharmacist.
- c) The cleanliness of DAA must be maintained through appropriate action (e.g. replacing inserts or replacing/discarding DAA when necessary or cleaning and sterilising any reusable parts and not re-using disposable components).

28. Rehder TL, McCoy LK, Blackwell B, et al. Improving medication compliance by counselling and special prescription container. *Am J Hosp Pharm* 1980; 37:379-85.

29. Pharmaceutical Society of Australia, *Professional Practice Standards*, op. cit., pp. 13-21.

5.2 Packing a DAA

When preparing a DAA for a consumer, a pharmacist must:

- a) dispense the medicines from the doctor's prescription;
- b) store the dispensed medicines in their original packs in a secure section of the DAA area where medicines will be protected from heat, light and moisture;
- c) pack the DAA using the consumer's current medicines treatment regimen as set out in the consumer's DAA Profile;
- d) check the packed medicines against the DAA Profile;
- e) ensure there is an audit trail so that all medicines can be tracked back to the original dispensing (e.g. date of dispensing, brand name and batch number);
- f) maintain a log of all DAA packed. Records maintained at or accessible by the pharmacy must include the initials of the dispensary assistant and / or pharmacist responsible for packing. If a dispensary assistant performs the packing the record must also include the initials of the pharmacist responsible for checking their work; and
- g) monitor any discrepancies that are detected in the packing process via a quality assurance system (see section 8).

The DAA must have labels that are clearly visible and carry information according to labelling requirements as outlined below in section 5.4.

5.3 Record keeping for DAA

Records should be maintained of each DAA packing, including the consumer's name and address, date of packing, date of provision, details of the medication provided (with cross reference to prescription numbers where appropriate) and some form of identification of the pharmacist involved. (Appendix 4 is a sample template of a record suitable for this purpose.) It is recommended that these records and DAA Profiles be retrievable for a minimum of six months after first being created.

5.4 Labelling of a DAA

The labelling of a DAA must comply with requirements of relevant legislation and pharmacy registering authority guidelines. A pharmacist who is responsible for packing a DAA must ensure that a DAA is labelled with:

- a) the name of the consumer;
- b) the name, address and telephone number of the pharmacy or pharmacy department;
- c) the brand and active ingredient names, strength and form of all medicines supplied in the DAA;
- d) the directions for use of each medicine, in plain English;
- e) the date on which the DAA was packed and the expiry date of the DAA;

- f) cautionary and advisory labels³⁰ for particular medicines where appropriate; and
- g) the words 'Keep out of reach of children'.

The labelling should enable identification of individual medicines. This can be achieved by inclusion of information on the colour, shape, size and manufacturer's marks for each medicine. Solid oral dose medicines (e.g. tablets, capsules) which cannot be identified should not be placed in a DAA with other medication or those that cannot be readily distinguished from each other should not be placed together in a DAA – except where the benefits outweigh the risks in which case the decision should be documented by the pharmacist as part of the risk assessment process. If photo identification of the medicine is required, this also must be attached.

5.5 Changes to a DAA

Changes to the contents of a DAA, after its original packing, should occur following the supply of appropriate documentation and only after formally establishing and documenting the changes. Changes should only be made under the direct supervision of a pharmacist and the changes should be checked by a pharmacist. A fax copy (outlining the request for changes) in accordance with State / Territory legislations and pharmacy registering authority guidelines, may be sufficient until the original copy can be obtained.

5.6 Third parties

Pharmacists must ensure that if a third party (e.g. a ADPS contractor) is involved in the packing of the DAA:

- a) the responsibilities of each party are set out in a written agreement describing aspects such as responsibility for dispensing, packing, and compliance with relevant legislation;
- b) the right of the consumer to privacy is understood by each party; and
- c) that consent is obtained from the consumer for this arrangement.

Pharmacists should note that ultimate responsibility and liability for the integrity of the DAA processes rests with the pharmacist who accepts the prescription from the consumer.

6. Medicines in DAA

When preparing and packing a DAA for a consumer, a pharmacist must maximise safety and quality aspects, and minimise the risks of instability of the medicines packed in a DAA while also balancing any risks of non-adherence. To do this, a pharmacist must address the following issues:

6.1 Medicines stability

Medicine stability is a broad term that encompasses chemical, physical, microbiological, therapeutic and toxicological stability not only of the drug substance but also the drug product (including excipients). Stability has been defined as the extent to which a product retains within specified limits and throughout the storage and use (i.e. its shelf life) the same properties and characteristics that it possessed at the time of its manufacture. Because the transfer of a medicine to a DAA is outside the terms of each product's registration licence required by a manufacturer, when repacking a medicine into a DAA, a pharmacist must consider the impact on drug stability due to the transfer to a DAA.³¹

Despite the widespread use of DAA there is little available data regarding the stability of medicines during packing or storage in DAA. In addition, there is no information on the stability of medicines when packed in close physical contact with other medicines. While pharmacists would be aware of general principles regarding the stability of medicines, there are no decisive rules that can be applied for each medicine to determine its suitability for packing in a particular DAA. Although some published work is available – see for example, UK-focussed guidance provided by Church and Smith³² – pharmacists must remain cautious and recognise the inherent limitations of such information.

A pharmacist must therefore make an informed judgment as to the suitability of any given medicine for inclusion in a DAA.³³ To do this it is recommended that a pharmacist adopt a 'risk assessment' approach using the available data and information, and using the following as a guide.³⁴ If the answer to any of following questions is 'no', transfer of the medicine to a DAA is *not* recommended:

- a) If the medicine poses occupational health and safety risks and requires special handling (e.g. solid dose cytotoxic agents, hormones, penicillin derivatives, teratogens), can the dose be packed in the DAA in a way which will protect pharmacy staff and consumers?
- b) If the medicine requires protection from heat (e.g. soft gel capsules), will the process used to seal the DAA protect the medicine from being adversely affected?

30. Pharmaceutical Society of Australia. The Australian Pharmaceutical Formulary and Handbook. (Current edition).

31. Stokes, Ientile, Roberts, op. cit., p. 44.

32. Church C, Smith J. How stable are medicines moved from original packs into compliance aids? *Pharm J* 2006; 276:75-81.

33. Stokes, Ientile, Roberts, op. cit., p. 45.

34. *ibid.*, p. 54.

- c) If the medicine requires protection from moisture (e.g. effervescent tablets, dispersible tablets, buccal tablets, sublingual tablets, and wafers), is the DAA moisture proof?
- d) If the medicine requires protection from light, is the DAA light proof?
- e) If the medicine is of a size or in a form which requires containment (e.g. a liquid) or a large compartment, can the DAA provide this?
- f) If the medicine requires protection from air, is the DAA airtight?
- g) If there are known interactions between the medicine and the packaging materials used in the DAA, can the medicine be protected from the packaging materials?

While it is generally not recommended that these types of medicines are packed, the pharmacist should assess the risks of instability when the medicine is packed in a DAA and the risks of non-adherence with a specific medicine if it is not packed in a DAA. In making decisions about packing medicines into a DAA, the DAA Profile confirmed by the pharmacist should provide documentary evidence of the application of this professional judgement. To assist with this process, pharmacists should maintain a record of medicines felt not to be stable in a DAA (see Appendix 5 for a sample). Pharmacists should add to this list if evidence or information on the instability of a medicine emerges in their DAA practice.

Where manufacturers advise that a medicine must remain in its primary packaging (e.g. foil) until just prior to ingestion, the risk of poor adherence must be weighed up against the risk of swallowing the medicine still in its packaging. This risk assessment should be documented in the DAA Profile and a risk management strategy documented and implemented. For example, the medicine could be packed in the DAA in its foil or blister pack with clear and specific instructions for the consumer to remove the medicine from its foil or blister pack prior to administration and with an explanation of the reasons for this recommendation. Processes should be included to confirm that this is understood and followed by the consumer. It should be noted that there have been reports of intestinal perforation caused by the swallowing of medicines in their blister or foil packs.

Once packing and checking the contents of a DAA have been completed the DAA should be sealed promptly.

After packing, the DAA should be protected from light and stored in a cool, dry place. Protection from light is not usually provided by the immediate packaging of the DAA system, so care is needed in this respect during storage within the pharmacy, while being transported and while the DAA is being used by the consumer in the home, residential facility or elsewhere.

6.2 Cytotoxics

If cytotoxic medicines are to be packed into a DAA, a unit dose system must be used unless there is strong evidence that the potential risks of poor adherence from not packing

the medicine or not packing the cytotoxic medicine in a multi-dose system outweighs the risks of exposure to cytotoxic medicines. This risk assessment should be documented in the DAA Profile and a risk management strategy documented and implemented.

Cytotoxic medicines must be handled in a manner which avoids skin contact, liberation of powdered drug into the air and contamination of other drugs. All equipment used in the preparation of DAA containing cytotoxic products must be labelled and used solely for that purpose. Counting machines should not be used.³⁵

Relevant professional guidelines and state occupational health and safety standards³⁶ should be observed when cytotoxic substances are handled. Pharmacists have a duty to adopt a risk management approach to identify any hazardous substances, assess the risk to health, control any risk to health associated with their contact, and safely dispose of those medicines when returned.

6.3 Controlled Drugs

The dispensing and packing of Controlled Drugs (Schedule 8 medicines) and the storage of DAA containing Controlled Drugs must be in compliance with relevant State / Territory legislation.

The cabinets in which DAA containing Controlled Drugs are stored must meet relevant legislative requirements and accommodate the packed DAA without physical damage.

6.4 Medicines ordered on an 'as required' basis

If a decision is made to pack a medicine which is required on an irregular or as required ('prn') basis it must be packed separately and clearly labelled as such. The quantity packed should not exceed the quantity that reasonably could be expected to be required during eight (8) weeks.^{37,38} The DAA should clearly show an expiry date of eight (8) weeks from the date of packing or the product's expiry date, whichever is the shortest period.

6.5 Maximum number of medicines per pack

The maximum number of items in each compartment should be assessed and limited so as to provide clear visibility for checking the packed DAA.

35. The Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Oncology. SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. *J Pharm Pract Res* 2005; 35(1): 44-52.

36. See for example: Victorian WorkCover Authority. Handling cytotoxic drugs in the workplace. 2003. Available at: www.worksafe.vic.gov.au/wps/wcm/resources/file/ebd87143a010b85/handling_cytotoxic.pdf

37. Anon. Report of the moisture permeability testing of monitored dosage systems. *Pharm J* 1994; 252:18-9.

38. Church, Smith, op. cit.

As the size and the number of solid oral dose forms (e.g. tablets, capsules) prescribed for each daily dosing time can vary, a pharmacist should use their professional judgement in deciding the maximum number of medicines or dose forms which should be placed in each compartment of a DAA, cognisant of:

- a) the visibility of all medicines when checking;
- b) possible damage to the contents if the medicines are packed too tightly; and
- c) possible physical or chemical interaction between medicines in close proximity to each other.

Vendors of DAA systems may be able to provide information on the optimum number of medicines or dose forms that can be packed in the DAA system they supply, which may also help minimise wastage in the event of any changes to the medicines or the regimen.

The DAA Profile confirmed by the pharmacist should provide documentary evidence of the application of this professional judgement.

6.6 Sealing DAA packs

The effect on medicines of temporary temperature spikes caused when a DAA is sealed via a heat sealing process, is uncertain. While the application of heat to seal a pack may be associated with a theoretical stability risk, it is recommended, that in the absence of conclusive evidence either way, pharmacists adopt a risk management approach and where possible, use a proprietary heat sealing device to produce a quick and reliable heat seal while minimising exposure to high temperatures.³⁹ The placing of heat sensitive presentations such as capsules at the base of the packing compartment (i.e. packed first) may also reduce any deleterious effect of heat sealing devices.

6.7 Child resistant packaging

The TGA's requirements⁴⁰ for child-resistant packaging must be noted when setting out medicines in DAA.

Blister-sealed DAA, cold-sealed cassettes and pouch packs produced by ADPS meet the child-resistant TGA packaging requirements. Blister and pouch packs are permitted as child-resistant packaging provided they are not formed from cellulose film or unlaminated paper. Some DAA do not meet the requirements of child-resistant packaging. These include dosette-type tablet organisers (or similar devices) where lids can be easily flipped open or where lids become worn and may fall open.

6.8 Time which medicines can be left in DAA

Although the data from a moisture permeation study published in the *Pharmaceutical Journal* needs to be interpreted with caution (as the evidence cannot necessarily be extrapolated), in the absence of more specific data, it is recommended that medicines should not be left in DAA for longer than eight (8) weeks from the date first packed until the last dose is taken.^{41,42} In some warm, humid climates, this maximum time may be shorter and pharmacists should use professional judgement in making these decisions. This maximum time may also be reduced by the inclusion of medicines with known storage limitations, e.g. thyroxine tablets.

Consumers should be advised to monitor packs for any deterioration of medicines in the pack such as change of colour or disintegration. If any deterioration is detected, the medicine should not be taken, and the DAA should be returned to the pharmacist for replacement if necessary.

PSA is aware of the various views on the issue of assigning an expiry date to a packed DAA and will continue to monitor new information as it becomes available.

6.9 Reuse of medicines

Unused medicines in DAA should be returned intact to the pharmacy for safe disposal and should not be reused. The pharmacist should discuss, with the consumer, or facility staff, and record in the DAA profile, the reason(s) for any unused medicines. Section 7.2 outlines the follow-up action which should be taken in regard to unused medicines.

A pharmacist must not return medicines to stock once they have been out of the pharmacy, nor use unused portions of packs of medicines dispensed for another consumer. It is unacceptable and unsafe practice for pharmacists to return to stock the unused portions of dispensed medicines that are returned by consumers, because there can be no assurance of the strength, quality, purity or identity of the products.

7. Monitoring

7.1 The monitoring process

Consumers using DAA should be monitored by their GP and pharmacist to ensure that any issues or problems which consumers might have when starting to use a DAA are detected and addressed. This should also occur on an on-going basis once the use of a DAA is established.

39. Stokes, lentile, Roberts, op. cit., p. 48.

40. Australian Government Department of Health and Ageing. Therapeutic Goods Administration. Therapeutic Goods Order No. 65. Child-resistant packaging for therapeutic goods. 5 August 2004. Available at: www.tga.gov.au/docs/html/tgo/tgo65.htm

41. Anon, op. cit.

42. Church, Smith, op. cit.

The pharmacist's role in monitoring should involve:

- a) recommending the consumer consult the GP for review, at regular intervals;
- b) asking the consumer to return DAA to prevent accumulation or hoarding of unused medicines and to allow for adherence monitoring (see section 7.2); and
- c) undertaking regular re-assessments at agreed intervals to ascertain medicine management ability, medicine knowledge and concordance in medicine regimen records.⁴³ This could involve a HMR. The re-assessment should be formally documented and may include items required under funded models.

processes. This includes a regular and documented monitoring program to ensure accurate packing.

Pharmacists need to implement, for example:

- a) staff training;
- b) communication audits;
- c) audit of correctness of DAA Profiles;
- d) packing and checking audits; and
- e) procedures for dealing with packing errors.⁴⁴

7.2 Non-adherence or decreasing ability to cope with DAA

Despite the use of a DAA, some consumers may remain (or become) incapable of good adherence. To help identify such consumers and address potential problems, the pharmacist (or delegated/supervised staff, as appropriate) should:

- a) advise the consumer to return existing packs to the pharmacist when new packs are supplied;
- b) note any medicines still in the pack and record details;
- c) ask the consumer if there are reasons why medicines haven't been taken, and record details;
- d) if appropriate, consider any changes which might improve adherence and discuss these with the consumer's GP; and
- e) if the pharmacist considers the use of a DAA is no longer appropriate, contact the GP as soon as possible to discuss the steps to be taken.

8. Quality assurance

To ensure a DAA service meets the safety and quality requirements of professional practice, a pharmacist should introduce procedures for quality control, quality assurance and monitoring of DAA provision. Audits should be carried out prior to the commencement of a DAA service and at six monthly intervals. The performance and results of these activities should be recorded together with any action taken, or outcome. The PSA professional practice standard on DAA Service should be used by pharmacists as a tool for self-assessment.

Good packing procedures should closely follow those of good manufacturing practice and incorporate quality

43. Stokes, Ientile, Roberts, op. cit., p. 78.

44. *ibid.*, p. 76.

Appendix 1: DAA service funded under the Fourth Community Pharmacy Agreement⁴⁵

Pharmacists delivering the DAA service under the Fourth Community Pharmacy Agreement must meet all relevant program requirements. For comprehensive information, pharmacists are referred to the Pharmacy Readiness Kit to be issued by the Pharmacy Guild of Australia, and the Operations Manual.

Pharmacists participating in the program will be assisted to provide DAA to a minimum number of patients who would benefit from the provision of a DAA.

A participating pharmacy must:

- a) be a Section 90 approved pharmacy;
- b) register, according to the program guidelines, for approval to become a registered DAA provider;
- c) have access to appropriate equipment and software to support DAA provision;
- d) have a location within the pharmacy that allows for a private patient interview to be conducted in accordance with professional pharmacy standards;
- e) agree to provide the DAA service in accordance with professional service standards and protocols for the Program;
- f) provide DAA to a minimum number of patients in line with the program guidelines;
- g) agree to collect and provide de-identified patient data, in line with the program guidelines, to inform future Program development and evaluation;
- h) perform mandatory self audits in line with the professional standards and guidelines, and the program guidelines; and
- i) agree to be audited for the purposes of verifying the above eligibility criteria.

The DAA devices that will be subsidised under this program will need to have tamper proof packaging, protect against contamination (e.g. disposable) and include drug and patient identification for individual compartments. Devices such as dosette-type containers that cannot be sealed or that do not have compartmentalised identification will not be covered by the program.

The subsidised supply of DAA to community patients will be limited to a conventional 7-day supply pack to promote interaction between the pharmacist and the patient and allow the pharmacist to monitor and assist the patient's medication management. Situations requiring supply for periods of longer than 7 days will be at the pharmacist's professional discretion and are expected to be the exception, rather than the rule.

45. Information extracted from the Dose Administration Aids Program Questions and Answers sheet (available at www.health.gov.au) issued by the Professional Programs and Services Advisory Committee, and updated with the assistance of staff of the Australian Government Department of Health and Ageing.

Guidelines and standards for pharmacists

Appendix 2: Assessment of consumer non-adherence when considering a DAA⁴⁶

The following modification of the Self Reported Morisky Score⁴⁷ is a validated tool for assessing if a consumer is unintentionally non-adherent with their medicines and can be used as a guide to whether an aid such as a DAA may assist the consumer to adhere to a medicine regimen.

Consumer's name: _____

Assessment date: _____

Assessed by: _____

Ask the consumer: "Thinking of the medicines *prescribed* for you by your doctor, please answer the following questions:"

Question	Answer (score) ⁴⁸	Consumer's answer and score
1. Do you ever forget to take your medicines?	No (0) Yes (1)	
2. Are you always careful about taking your medicines?	No (1) Yes (0)	
3. When you feel better do you sometimes stop taking your medicines?	No (0) Yes (1)	
4. Sometimes, if you feel worse when you take your medicine, do you stop taking them?	No (0) Yes (1)	
	Total score	
Other comments / notes		

Explanation of scores

- Total score of 0 Adequate adherence
Total score of 1 – 4 Inadequate adherence (partial adherence or non-adherence)
- Consumers who score '2' from the first two questions may benefit from a DAA more than consumers who score less than '2' from these two questions.

46. This template form is available as a Word document which can be downloaded from PSA's web site (www.psa.org.au – see under "Policies and Guidelines").

47. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care* 1986; 24(1):67-73.

48. It has been suggested that modifying the assessment by using a 5-point Likert scale [i.e. never (0), rarely (1), sometimes (2), often (3), always (4)] instead of a binary scale (Yes / No) may improve the accuracy of assessment.

Guidelines and standards for pharmacists

Appendix 3: Discussion guide and sample agreement for a DAA Service^{49,50}

The following is a list of topics and issues designed to be used as a guide in a discussion with a consumer where the use of a DAA is being considered. Pharmacists should use their professional judgement in deciding the relevance of each issue to individual consumers. This discussion guide may form the basis of an agreement between a consumer and a pharmacist on the details of the DAA service to be provided. Pharmacists are encouraged to modify this sample agreement to meet their DAA service needs. A copy of this agreement should be provided to the consumer's GP for their information.

Consumer	Pharmacy providing the DAA service
Name:	Name:
Address:	Address:
Telephone no.:	Telephone no.:
Medicare number:	Name of pharmacist:
Concession card details:	Consumer's GP
Name of carer and telephone no.:	
Other details:	
	Name:
	Address:
	Telephone no.:

Signed:

Consumer: _____ Pharmacist: _____

Date: _____ Date: _____

Note: The options given in parentheses under 'Issues' are examples only.

Issues	Agreed terms
Consent	
The consumer consents to the sharing of medicine-related information between the pharmacist and the consumer's doctors, hospitals or community nurse as relevant (yes / no):	
The consumer consents to an assessment of their management of the DAA every six months (yes / no) or at agreed intervals of:	
DAA service costs	
The cost of medicines is additional to the DAA service. The person responsible for payment of medicines which are to be packed in a DAA is (consumer / carer / other):	
The cost of the DAA service (per week / per month / per DAA / other) is:	
The person responsible for payment of the DAA service is (consumer / carer / other):	
Payment for the DAA service will be (invoiced / on account / paid at time of collection of DAA):	
Prescriptions	
The pharmacy staff responsible for ensuring a valid prescription is available for the medicines to be packed into a DAA is:	
The person responsible for providing a valid prescription (where required) for medicines to be packed in a DAA to the pharmacist in advance of the scheduled packing day is (consumer / GP / facility staff / other):	

49. Adapted from: Stokes, Ientile, Roberts, op. cit., p. 70.

50. This template form is available as a Word document which can be downloaded from PSA's web site (www.psa.org.au – see under "Policies and Guidelines").

Guidelines and standards for pharmacists

Issues	Agreed terms										
The pharmacist will remind the consumer to obtain a new prescription from the GP (yes / no):											
The pharmacist will generate reminder notices to the GP to provide prescription(s) (yes / no):											
The GP is willing to provide a prescription for on-going medicines without a formal consultation (appointment) with the consumer (yes / no):											
If a prescription has to be dispensed at another pharmacy or pharmacy department, the procedure to ensure that this pharmacy has the medicines for packing into the DAA is:											
The procedure to be followed if there is no prescription available for the pharmacist to dispense is:											
DAA service details											
The brand or type of DAA supplied is:											
The number of days' supply of regular medicines for each DAA packed is:											
The medicines to be packed in a DAA are: <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">1.</td> <td style="width: 50%;">6.</td> </tr> <tr> <td>2.</td> <td>7.</td> </tr> <tr> <td>3.</td> <td>8.</td> </tr> <tr> <td>4.</td> <td>9.</td> </tr> <tr> <td>5.</td> <td>10.</td> </tr> </table>	1.	6.	2.	7.	3.	8.	4.	9.	5.	10.	
1.	6.										
2.	7.										
3.	8.										
4.	9.										
5.	10.										
The procedure to be followed If there is a need for more than the usual number of packs to be supplied (e.g. consumer going on holidays) is:											
The date and time when the DAA can be collected will be advised (by telephone when ready / when the prescription is provided to the pharmacist / other):											
The DAA will be (delivered / collected) by (pharmacy staff / consumer / facility staff):											
The procedure to be followed if the DAA is damaged, destroyed or incorrectly opened is:											
Unused medicines in a DAA, empty DAA and expired DAA will be returned to the pharmacist by (consumer / carer / facility staff / other):											
Changes to medicines											
The GP is responsible for authorising changes to medicines. The person responsible for informing the pharmacist of medicine changes is (GP / consumer / facility staff):											
Changes to medicines (i.e. dose, frequency, duration, or the commencement or cessation of a medicine) will be conveyed in writing by the GP (yes / no):											
The urgency of the need to change the DAA to accommodate the changes to the medicine regimen will be conveyed to the pharmacist by (GP / consumer / facility staff):											
If changes to medicines in the pack need to be made before the current DAA pack is finished, the procedure to be followed to ensure this occurs is:											
Other notes / comments											

Guidelines and standards for pharmacists

Appendix 4: Record of packing dispensed medicines into DAA⁵¹

Name: _____ Address: _____

Medicine name / form / strength	Original prescription dispensed			DAA packing			
	Date dispensed & prescription no.	Quantity dispensed	Batch no. and expiry date	Date: Quantity packed	Initials of packer & pharmacist	Date: Quantity packed	Initials of packer & pharmacist

51. This template form is available as a Word document which can be downloaded from PSA's web site (www.psa.org.au – see under "Policies and Guidelines").

Guidelines and standards for pharmacists

Appendix 5: Examples of medicines which should not be packed in DAA^{52,53,54}

Guidance on the stability of medicines in DAA systems is very limited. From the manufacturer's viewpoint, the removal of any drug from the environment in which it has undergone stability testing, to one where it has not, reduces or invalidates the shelf life indicated on the label. It should be noted that different manufacturers sometimes have varying guidance for the same or similar products. **In many cases the pharmacist packing DAA will have to make a judgement on the advisability of incorporating products in them, in the absence of hard information.** The pharmacist will need to make a risk assessment on the basis of individual medicines and individual consumers. Reference to Section 6.1 'Medicines stability' is recommended.

It is imperative that consumers are advised of the medicines which are not packed in the DAA and the labelling which is used to remind consumers to take unpacked medicines.

Pharmacists may wish to use this template to create their own list. Any such list must be updated regularly and appropriate reference sources recorded.

Type of tablet	Examples	Reference source
Effervescent tablets	e.g. effervescent forms of ranitidine, cimetidine, potassium chloride, soluble aspirin tablets	
Dispersible tablets	e.g. piroxicam dispersible tablets	
Buccal tablets	e.g. nystatin lozenges	
Sublingual tablets	e.g. glyceryl trinitrate sublingual tablets, buprenorphine HCl sublingual tablets	
Chewable tablets	e.g. Vitamin C	
Hygroscopic tablets	e.g. sodium valproate	
Tablets exceedingly susceptible to light degradation	e.g. nifedipine, tamoxifen	
Heat sensitive tablets		
Tablets containing aluminium hydroxide, magnesium trisilicate	e.g. Gaviscon®	
	Hexamine hippurate tablets	
	Omeprazole (unless packed monthly)	
Moisture-sensitive medicines	Wafer presentations e.g. olanzapine	
Other medicines where limited time in DAA may be appropriate	Thyroxine	

52. Church, Smith, op. cit.

53. Adapted from: Nomad Pharmacy Manual <http://www.nomad.co.nz/support/manuals/pharmmanicare.htm>.

54. This template form is available as a Word document which can be downloaded from PSA's web site (www.psa.org.au – see under "Policies and Guidelines").