

Standards for the Provision of *Pharmacy*

Medicines and *Pharmacist Only*

Medicines in Community Pharmacy

Revised, November 2005



These Standards were originally developed in 1998 by a collaborative research project team from the Department of Pharmacy, University of Sydney (Prof. Charlie Benrimoj and Melissa Crampton) and the School of Pharmacy and Medical Sciences, University of South Australia (Assoc. Prof. Andy Gilbert and Neil Quintrell). The project was funded by the Commonwealth Department of Health and Family Services through the Pharmacy (Agreement) Projects Consultative Committee. The Pharmaceutical Society of Australia was involved in the dissemination of this publication to the profession.

The Standards were revised in 2005 by a research project team from the Faculty of Pharmacy, University of Sydney (Prof. Charlie Benrimoj and Frances Wilson). The project was funded by the Australian Government through the Pharmacy Development Program of the Third Community Pharmacy Agreement.

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1. Introduction

1a. Background

The standard of professional service provided to the community in the handling of *Pharmacist Only* and *Pharmacy* medicines is of increasing importance. There appears to be a growing trend in Australia for consumers to self-medicate with over-the-counter medications for common ailments. This is potentially due to shifts in consumer preferences towards self-care and self-responsibility for health and the emerging trend for the government to reschedule prescription medicines to non-prescription status. These changes have significant implications for community pharmacy. Community pharmacies are in a unique position to support consumers' purchases of these medicines through the application of pharmacists' expert knowledge, with the support of trained staff, in an environment in which due regard is given to facilitating appropriate use.

Pharmacy Medicines (S2) are substances or preparations for therapeutic use which are substantially safe in use but where advice or counselling is available if necessary, and are for minor ailments and symptoms which can be easily recognised by the consumer and do not require medical diagnosis or management.¹ *Pharmacist Only (S3) Medicines* are substances or preparations for therapeutic use which are substantially safe in use but require professional advice or counselling by a pharmacist; the use of which requires pharmacist advice, management or monitoring; and are for minor ailments and symptoms which can be identified by the consumer and verified by a pharmacist, and do not require medical diagnosis or only require initial medical diagnosis, and do not require close medical management.¹

The decision to establish the original national standards of practice for community pharmacy in the handling of *Pharmacist Only* and *Pharmacy* medicines followed the 1996 release of the Industry Commission Report which examined the efficacy of existing medicine scheduling arrangements in Australia.² The Commission recommended that the current scheduling for *Pharmacist Only* and *Pharmacy* medicines should be retained, *'pending further research into the role of pharmacist counselling in ensuring improved health outcomes'*.

In response to this recommendation, the Commonwealth Department of Health and Family Services commissioned a research project, funded through the Third Community Pharmacy Agreement Development Program, to develop a model that incorporates Standards of Practice, Standard Operating Procedures, Protocols and training programs for community pharmacists and pharmacy assistants. The result of this research project was the 1999 publication of a set of Standards, the Standards for Provision of *Pharmacist Only* and *Pharmacy* Medicines in Community Pharmacy.³ The Standards aimed to optimise pharmacy practices in the provision of *Pharmacist Only* and *Pharmacy* medicines and ensure that all community pharmacies provide appropriate and consistent professional advice.

The Standards were published by the Pharmaceutical Society of Australia and included in the Quality Care Pharmacy Program (QCPP) (as POP Standards). QCPP is an industry-developed quality assurance program developed by the Pharmacy Guild of Australia. The QCP Program is an integrated system of performance standards and supporting tools and processes. QCPP is based on business and professional standards that have been developed by both the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.⁴ The program has been embraced by Australian community pharmacies; in September 2005, eighty-seven percent of Australian Pharmacies were QCPP accredited.⁵

This revised version of the Standards has been developed in conjunction with the revision of the QCPP program and the revision of the Pharmaceutical Society of Australia (PSA) Professional Practice Standards. It has been informed by a number of different sources. For the purposes of this introduction, the document Standards for Provision of *Pharmacist Only* and *Pharmacy* Medicines in Community Pharmacy³ will be referred to as the Original Standards, and this document will be referred to as the Revised Standards.

Firstly, in response to obligations under the Competition Principles Agreement of 1995, all heads of government agreed to a review of legislation governing drugs, poisons and controlled substances. The 2001 report from this review (The Galbally Review) advocated a focus on the consumer rather than on the product. It recommended that a risk-based code of practice could ensure that more effective counselling was provided when necessary, not because of the products schedule 'but because for that consumer the risk-based triggers were activated' and that 'the triggers which should elicit pharmacist intervention should focus more on the particular consumer than on the substance'.⁶ Galbally noted that, in many cases, the risk to an individual purchasing a *Pharmacy Medicine* may be as high or higher than the risk to a person purchasing a *Pharmacist Only Medicine*. In other words, the risk relates more to the individual circumstances of the consumer and the way the consumer uses the medicine than to the absolute toxicity of the substance.⁶ Additionally, it has been noted that while significant data exist on the rate of adverse events in hospitals, there are no reliable statistics from other areas of health care.⁷ Consumer safety in settings such as a community pharmacy is of paramount concern, and although much of the focus on medication safety relates to prescribed medicines, there are no doubt risks associated with use of non-prescription medicines. Adverse medicines events are responsible for 1.6% of all hospital admissions.⁸ Accordingly, this version of the standards approaches the supply of both *Pharmacy Medicines* and *Pharmacist Only Medicines* from the same consumer-centred approach.

A recent research project funded by the Australian Government Department of Health and Ageing as Part of the Third Community Pharmacy Agreement, the 'Cost –Benefit Analysis of Pharmacist Only and Pharmacy Medicines and a Risk Based Evaluation of the Standards', responded to the Galbally Report and included an assessment of the Original Standards from a Risk Management Perspective. The recommendations pertaining to the Original Standards were that National Policy and Protocols should be developed concentrating on when and how pharmacy assistants should refer at-risk consumers to pharmacists and that these policies should be incorporated into the 'Standards'. In addition, it recommended that consideration should be given to developing further guidelines within the Standards to assist community pharmacy staff in better identifying, assessing and documenting risk so that the Standards appropriately meet best practice risk management processes. Further, it recommended that consideration should be given to increasing the external audit component of the monitoring of the Standards to provide greater certainty of their effectiveness.⁹

Additional discussion with the risk management consultant responsible for reviewing the Original Standards and making the above recommendations, identified that in order to introduce risk management more completely into the Standards, the review team must ensure that the Standards are both objective and measurable and that there is a defined framework for pharmacists and pharmacy assistants to assess individual consumer risk.¹⁰ To that end, a major objective of the Revised Standards was to incorporate these recommendations.

The Revised Standards also incorporates reference to the *Competency Standards for Pharmacists in Australia*.¹¹ Competency is described as the "*skills, attitudes and other attributes attained by and individual based on knowledge and experience which together are considered sufficient to enable the individual to practice as a pharmacist.*"¹¹ Professional Practice standards are not the same as competency standards, they relate instead to the policies, procedures and tools used to achieve a certain practice. Therefore, in this document, significant effort has been made to integrate the two. For example, standards that relate to training have been linked to competency checklists.



Finally, and perhaps most importantly, the Revised Standards are intended to be an interactive document focusing on the behaviours required by all pharmacy staff (including pharmacists, pharmacy assistants, and pharmacy/dispensary technicians) to actively meet each standard. This is a document that pharmacy staff can interact with and use in a practical way. Each individual standard provides clear advice on how to implement it in practice with a list of required actions and behaviours and detailed implementation notes. A variety of materials, including examples of reference tools, policies and procedures are also provided to assist in this process.

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References

1. Australian Health Ministers Advisory Council. 1997. *Guidelines for National Drugs and Poisons Schedule Committee*. Canberra: Australian Health Ministers' Advisory Council.
2. Industry Commission. 1996. *The Pharmaceutical Industry: Vol 1 and 2*. Canberra: Australian Government Publishing Service. Industry Commission Report No 51.
3. Pharmaceutical Society of Australia. 1999. *Standards for the Provision of Pharmacy and Pharmacist Only Medicines*. Canberra: Pharmaceutical Society of Australia.
4. Pharmacy Guild of Australia. 1998. *Quality Care Pharmacy Program: Pharmacy Standards*. Canberra: Pharmacy Guild of Australia.
5. QCPP Website. September 2005. http://www.qcpp.com/list_accredited_pharmacies.htm
6. Galbally R. 2001. *Final report of the review of drugs, poisons and controlled substances legislation (Galbally Report)*. Woden ACT: Secretariat, Review of Drugs, Poisons and Controlled Substances Legislation.
7. Braithwaite J, Healy J, Dwan K. 2005. *The Governance of Health Safety and Quality*. Canberra: The Commonwealth of Australia.
8. Australian Pharmaceutical Advisory Council. 2005. *Guiding principles to achieve continuity in medication management*. Canberra: The Commonwealth of Australia.
9. Benrimoj SI. et al. 2005. *Final Report: A Cost Benefit Analysis of Pharmacist Only (S3) and Pharmacy Medicines (S2) and Risk-Based Evaluation of the Standards*. University of Sydney: <http://beta.guild.org.au/research>
10. Personal Communication with John Kelly. John G Kelly & Associates Pty Ltd. September 2005.
11. Pharmaceutical Society of Australia. 2003. *Competency Standards for Pharmacists in Australia*. Canberra: Pharmaceutical Society of Australia.



1b. How to read and use the standards

The following sample standard will outline the structure and intent of the information contained in the standards document.

Short name of standard

Standard #.	A simple sentence that encapsulates what the standard covers
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Criterion #	This statement describes ongoing actions that the pharmacy needs to do to ensure that a part of the Standard is being met.
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Indicator	Required Actions & Behaviours:	
	1 These statements describe a number of actions you have to take and behaviours you need to adopt to ensure that you meet the associated criterion.	<input type="checkbox"/>
	2 Typically these statements will ask you to Confirm, Develop & Maintain, Determine, or Provide.	<input type="checkbox"/>
	3 As a self-assessment tool, you can use these boxes to either tick, cross or mark N/A c (not applicable).	<input type="checkbox"/>

Implementation Notes:

Materials available to assist in meeting the Criterion

The materials are examples of Policies, Procedures and Tools you may use in order to meet the standard.

- POLICIES (POL) outline WHY a Standard is in place,
- PROCEDURES (PROC) outline HOW to do something required by the Standard and
- TOOLS provide templates for any additional documents that need to be developed in order to meet the standard.

These materials conform to minimum practice requirements. Individual pharmacies may choose to alter or augment these materials – **however, the new or updated version must be no less rigorous than the sample provided.**

Each Policy, Procedure or Tool is named using a 3-part system:

- letters referring to the type of document (POL, PROC, or TOOL)
- a number referring to the Standard it relates to and
- a letter referring to the position of the document within the Standard.

For example, the first Procedure associated with Standard 4 is 'Proc 4A'.

Evidence required at Assessment

- This section details the evidence required for assessment of the criterion. It will typically ask for 'Proof of' or an 'Explanation of' of a particular procedure or document.
- Some proof will be supplied by documentation; other proof will be obtained through observation.
- Additional Proof can be gathered via performance in a pseudo-patient visit.

Summary of Standards

1. Resources

Standard 1

The pharmacy has adequate resources to consistently promote the quality use of Pharmacy Medicines and Pharmacist Only Medicines.

2. Staff training

Standard 2

All staff members who supply Pharmacy Medicines and Pharmacist Only Medicines receive initial and ongoing training on products, services, and procedures relevant to their supply.

3. Location and signage

Standard 3

Pharmacy Medicines and Pharmacist Only Medicines are located in areas of the pharmacy that indicate that they are not normal items of commerce, and are consistent with scheduling classifications.

4. Consumer care and advice

Standard 4

Consumers receive care and advice, appropriate to their presentation and need, that will facilitate the quality use of Pharmacy Medicines and Pharmacist Only Medicines.

5. Documentation

Standard 5

The pharmacy documents the provision of Pharmacist Only Medicines to ensure continuity of care and enhance optimal health outcomes.

6. Rights and needs of consumers

Standard 6

All staff members respect the rights & needs of all consumers.



1. Resources

Standard 1 **The pharmacy has adequate resources to consistently promote the quality use of Pharmacy Medicines and Pharmacist Only Medicines.**

Criterion 1 **The layout and design of the pharmacy allows for the existence of a Professional Services Area (or areas).**

Indicator	Required Actions & Behaviours:	
	1 Maintain a section or section/s of the pharmacy designated as a 'Professional Services cArea' (or areas).	<input type="checkbox"/>
	2 Ensure that only health-related products are stored in the 'Professional Service Area/s'.	<input type="checkbox"/>

Implementation Notes:

Evidence Required for Assessment

- Visual proof that the 'Professional Services Area/s' exist.
- Visual proof that only health-related products are stored in the 'Professional Services Area/s'.

Criterion 2 **There are adequate resources to ensure that consumers have timely access to pharmacy staff for advice on the treatment of symptoms and the appropriate selection of Pharmacy Medicines.**

Indicator	Required Actions & Behaviours:	
	1 Maintain an adequate staffing level and/or redesign workflow and/or reallocate work duties as necessary.	<input type="checkbox"/>

Implementation Notes:

Evidence Required for Assessment

- Explanation of how the staffing level, workflow and allocation of work duties provides sufficient resources to maintain timely access to Pharmacy Staff.
- Performance at a pseudo-patient visit (time elapsed between entering the pharmacy and speaking to a staff member).

Criterion 3 **There are adequate resources to ensure that consumers have timely access to a pharmacist for advice on the treatment of symptoms and the appropriate selection of Pharmacist Only Medicines, and where necessary, Pharmacy Medicines.**

Indicator

Required Actions & Behaviours:

- | | | |
|---|--|--------------------------|
| 1 | Maintain an adequate staffing level and/or redesign workflow and/or reallocate work duties as necessary. | <input type="checkbox"/> |
| 2 | Develop and Maintain a Procedure 'Referring a Consumer to the Pharmacist' for handling consumers who require access to the pharmacist. | <input type="checkbox"/> |
| 3 | Confirm that all staff members are trained in the use of this procedure. | <input type="checkbox"/> |

Implementation Notes:

Materials available to assist in meeting the Criterion

Procedure (PROC 1A): Referring a Consumer to the Pharmacist

Evidence Required for Assessment

- Explanation of how the staffing level, workflow and allocation of work duties provides sufficient resources to maintain timely access to the pharmacist.
- The Procedure 'Referring a Consumer to the Pharmacist'
- Performance at a pseudo-patient visit (time elapsed between entering the pharmacy and speaking to a pharmacist).



Criterion 4 **Pharmacists have timely access to current sources of expert advice on clinical matters relating to the provision of Pharmacist Medicines and Pharmacist Only Medicines.**

Indicator

Required Actions & Behaviours:

- 1 Develop a list of current clinical information sources that are accessible in the pharmacy (Clinical Reference List). ☐
- 2 Maintain these information sources to ensure that they are current and comprehensive. ☐
- 3 Confirm that all pharmacists are aware of the 'Clinical Reference List'. ☐

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool 1A: Clinical Reference List

State Legislation and Regulations.

Evidence Required for Assessment

- The 'Clinical Reference List'.
- Random sample of access to five items on the 'Clinical Reference List' (including web-based items).

Criterion 5 **Consumers have access to current information on Pharmacy Medicines and Pharmacist Only Medicines and related conditions.**

Indicator	Required Actions & Behaviours:	
	1 Develop a list of information sources for consumers on non-prescription medicines and related conditions that are available in the pharmacy (Consumer Reference List).	<input type="checkbox"/>
	2 Maintain these information sources regularly to ensure that they are current and comprehensive.	<input type="checkbox"/>
	3 Provide consumers with access to these materials.	<input type="checkbox"/>
	4 Confirm that all staff are aware of the 'Consumer Reference List'.	<input type="checkbox"/>

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool 1B: Consumer Reference List

Evidence Required for Assessment:

- Visual Proof of the availability of prominently displayed information.



2. Staff Training

Standard 2 All staff members who supply Pharmacy Medicines and Pharmacist Only Medicines receive initial and ongoing training on products, services, and procedures relevant to their supply.

Criterion 1 Each staff member that supplies Pharmacy Medicines and/or Pharmacist Only Medicines has a training plan. This plan should record the training needs relevant to the position that they hold.

Indicator

Required Actions & Behaviours:

- 1 Determine the competencies associated with each position and the training required to achieve those competencies. ☐
- 2 Develop and Maintain an individualised training plan for each staff member. ☐
- 3 Confirm that each staff member is aware of his or her training plan. ☐

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool 2A: Competency Checklists

Tool 2B: Training Plan & Record

Evidence Required for Assessment

- A training plan for every staff member who supplies Pharmacy Medicines and/or Pharmacist Only Medicines.

Criterion 2 All staff members are aware of training opportunities, particularly those that are consistent with their individualised training plans.

Indicator	Required Actions & Behaviours:
	1 Determine the best way to advertise training opportunities to pharmacy staff. <input type="checkbox"/>
	2 Confirm that this process is followed. <input type="checkbox"/>

Implementation Notes:

Evidence Required for Assessment

- Explain the process for advertising training opportunities to pharmacy staff.

Criterion 3 Each staff member that supplies Pharmacy Medicines and/or Pharmacist Only Medicines attends training that is relevant to the supply of these medicines.

Indicator	Required Actions & Behaviours:
	1 Ensure that pharmacy staff attend training as outlined in their training plan. <input type="checkbox"/>

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool 2B: Training Plan & Record

Evidence Required for Assessment

- The completed training record for every staff member that supplies Pharmacy Medicines and/or Pharmacist Only Medicines.



Criterion 4 **Each staff member has an up-to-date training record that details all relevant Pharmacy Medicines and/or Pharmacist Only Medicines training that they have undertaken.**

Indicator

Required Actions & Behaviours:

- | | | |
|---|---|--------------------------|
| 1 | Ensure that training records exist. | <input type="checkbox"/> |
| 2 | Confirm that training records are up-to-date. | <input type="checkbox"/> |

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool 2B: Training Plan & Record

Tool 2C: Training Summary Sheet

Evidence Required for Assessment

- The completed training record for every staff member that supplies Pharmacy Medicines and/or Pharmacist Only Medicines.

3. Location and Signage

Standard 3 Pharmacy Medicines and Pharmacist Only Medicines are located in areas of the pharmacy that indicate that they are not normal items of commerce, and are consistent with scheduling classifications.

Criterion 1 Pharmacist Only Medicines are located in a secure area*.

Indicator

Required Actions & Behaviours:

- 1 Confirm that Pharmacist Only Medicines are located in a secure area that: ☐
 - Is within sight, hearing and supervision of the pharmacist.
 - Consumers do not have direct access to.
 - Consumers are unable to self-select from.

* Certain State Regulations may have additional storage requirements for Pharmacist Only Medicines. In order to meet these standards, these additional requirements must be met.

Implementation Notes:

Evidence Required for Assessment

- Visual proof that this secure area exists and that all Pharmacist Only Medicines are located within it.
- Visual Proof that no Pharmacist Only Medicine is located outside this secure area.



Criterion 2 Pharmacy Medicines are located in the defined 'Professional Services Area/s'*.

Indicator	Required Actions & Behaviours:	
	1 Maintain a section or section/s of the pharmacy designated as a 'Professional Services Area' (or areas).	<input type="checkbox"/>
	2 Ensure that only health-related products are stored in the 'Professional Service Area/s'. (Cross Reference: Standard 1, Criterion 1: Professional Services Area/s).	<input type="checkbox"/>
	3 Confirm that all Pharmacy Medicines are located in a 'Professional Services Area/s'.	<input type="checkbox"/>

* Certain State Regulations may have additional storage requirements for Pharmacy Medicines. In order to meet these standards these additional requirements must be met.

Implementation Notes:

Evidence Required for Assessment

- Visual proof that the 'Professional Services Area/s' exist.
- Visual proof that all Pharmacy Medicines are stored in the 'Professional Services Area/s'.

Criterion 3 Signage in the pharmacy encourages consumers to seek advice from Pharmacy Staff regarding Pharmacy Medicines and related conditions.

Indicator	Required Actions & Behaviours:	
	1 Develop and Maintain a system of signage within the pharmacy that encourages consumers to seek advice, particularly within the 'Professional Services Area/s' (shelf talkers, posters or custom made signs displayed prominently).	<input type="checkbox"/>

Implementation Notes:

Evidence Required for Assessment

Visual proof that such a system of signage exists within the pharmacy (shelf talkers, posters or custom made signs displayed prominently).

Criterion 4 **Any items identified as being subject to inappropriate use are stored in an area that is under the direct supervision of a pharmacist.**

Indicator

Required Actions & Behaviours:

- 1 Identify and list items that may be subject to inappropriate use. ☐
‘Inappropriate use’ means either medicines being sought and/or taken for the wrong purpose; consistent use of medicines that may indicate the presence of untreated medical conditions; or medicines taken solely to support dependency.
- 2 Store these items in an area that is under the direct supervision of a pharmacist. ☐

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool (Tool 3A): Items That May be Subject to Inappropriate Use.

Evidence Required for Assessment

- A list of ‘Items That May be Subject to Inappropriate Use’.
- Visual proof that all items on the list above are stored in an area that is under the direct supervision of a pharmacist.



4. Consumer Care and Advice

Standard 4 Consumers receive care and advice, appropriate to their presentation and need, that will facilitate the quality use of Pharmacy Medicines and Pharmacist Only Medicines.

- Criterion 1** Systems are in place that assist pharmacy staff to:
- **ENGAGE** consumers in conversation,
 - **GATHER** appropriate and adequate clinical information from each consumer who
 - o Presents with a symptom, or
 - o Requests/Self-selects a Pharmacy Medicine or Pharmacist Only Medicine,
 - **ANALYSE** the information gathered and determine the most appropriate action to take, and
 - **RESPOND** with appropriate care and advice.

Indicator	Required Actions & Behaviours:
	<ol style="list-style-type: none"> 1 Develop and Maintain a procedure for 'Responding to Consumer Requests'. <input type="checkbox"/> Note: This procedure must indicate when a pharmacy assistant should refer a consumer to the pharmacist and when a pharmacist should refer a consumer to another health care professional. 2 Develop and Maintain Protocol/s for Responding to Consumer Requests that incorporate the information in the Tool 'Elements of a Protocol for Responding to Consumer Requests'. <input type="checkbox"/> 3 Confirm that all staff members have been trained in the procedure and the protocol. <input type="checkbox"/>

Implementation Notes:

Materials available to assist in meeting the Criterion

Procedure (Proc 4 A): Responding to Consumer Requests

Tool (Tool 4A): Elements of a Protocol for Responding to Consumer Requests

Tool (Tool 4B): Sample Protocols: 'What Stop Go' and 'CARER'

Evidence Required for Assessment

- The Procedure 'Responding to Consumer Requests'.
- The Protocols used by staff members for Responding to Consumer Requests.
- The Individual Staff Training Records (Cross Ref: Standard 5: Training) showing that they have completed training in using the procedure 'Responding to Consumer Requests' and in the use of Protocols.
- Performance at a pseudo-patient visit.



Criterion 2 **Pharmacy Staff who are trained in the supply of Pharmacy Medicines and Pharmacist Only Medicines are visible and approachable in the defined Professional Services Area/s.**

Indicator

Required Actions & Behaviours:

- 1 Confirm that Pharmacy Staff are visible and approachable for consultation in the Professional Services Area/s at all times. ☐
- 2 Confirm that Pharmacy Staff who are located in the Professional Services Area/s are trained in the handling of Pharmacy Medicines and Pharmacist Only Medicines. ☐

Implementation Notes:

Materials available to assist in meeting the Criterion

(Cross Reference: (Tool 2B) Training Plan and Record Template)

Evidence Required for Assessment

- Performance in a pseudo-patient visit (pharmacy staff are visible and approachable in the 'Professional Services Area/s').
- A completed 'Training Record' for a sample of up to three staff members located in the 'Professional Services Area' at the time of assessment showing that they have completed training in the supply of Pharmacy Medicines and Pharmacist Only Medicines.

Criterion 3 **Consumers whose medical conditions warrant further investigation are referred to an appropriate health care professional.**

Indicator

Required Actions & Behaviours:

- 1 Develop and Maintain a procedure for 'Responding to Consumer Requests'. ☐
- 2 Confirm that all staff members have been trained in using the procedure. ☐

Implementation Notes:

Materials available to assist in meeting the Criterion

Procedure (Proc 4 A): Responding to Consumer Requests

Evidence Required for Assessment

- The Procedure 'Responding to Consumer Requests'.
- The Individual Staff Training Records (Cross Ref: Standard 2: Training) showing that staff have been trained in the use of this procedure.
- Performance at a pseudo-patient visit.

Criterion 4 **Pharmacist Only Medicines are provided to consumers with the direct involvement of the pharmacist and according to State Legislative requirements**

Indicator

Required Actions & Behaviours:

- 1 Confirm that all staff are aware of the requirement for pharmacists to be involved in the supply of Pharmacist Only Medicines. ☐

Implementation Notes:

Evidence Required for Assessment

- Performance at a pseudo-patient visit (was the pharmacist involved if it was a Pharmacist Only Medicine request/supply).



5. Documentation

Standard 5 The pharmacy documents the provision of Pharmacist Only Medicines to ensure continuity of care and enhance optimal health outcomes.

Criterion 1 The pharmacy maintains a record management system for Pharmacist Only Medicines that conforms to relevant legislative requirements.

Indicator	Required Actions & Behaviours:	
	1 Develop and Maintain a documentation policy for Pharmacist Only Medicines that conforms with relevant legislative requirements. Confirm that all staff are aware of and have access to the Pharmacist Only Medicine Documentation Policy.	<input type="checkbox"/>
	2 Develop and Maintain a list of recordable Pharmacist Only Medicines that conforms with relevant legislative requirements. Confirm that all staff are aware of and have access to this list.	<input type="checkbox"/>
	3 Develop and Maintain a system for recording the supply of recordable Pharmacist Only Medicines that conforms with relevant legislative requirements. Confirm that all staff are aware of this system.	<input type="checkbox"/>

Implementation Notes:

Materials available to assist in meeting the Criterion

Policy (Pol 5A): Pharmacist Only Medicine Documentation.

Tool 5A: List of Recordable Pharmacy Medicines and Pharmacist Only Medicines

Evidence Required for Assessment

- The Policy 'Pharmacist Only Medicine Documentation'.
- A 'List of Recordable Pharmacy Medicines and Pharmacist Only Medicines'. Proof that this list is up-to-date and easily accessible.
- Proof that the policy is being followed. Provide an example of documentation for a random sample of two items on the 'List of Recordable Pharmacy Medicines and Pharmacist Only Medicines'.
- Proof that the actual records kept are easily accessible and sufficiently detailed to allow review.

Criterion 2

Pharmacist Only Medicine documentation must be kept in a format that is readily retrievable and accessible. It must be sufficiently detailed to enable subsequent review and/or follow up by another pharmacist.

Indicator

Required Actions & Behaviours:

- 1 Confirm that when a consumer has a medication profile at the pharmacy, and with the consumers agreement, the purchase of Pharmacist Only Medicines is recorded in the consumer's file. Recording these items will assist in the identification of any interactions with prescribed medicines. ☐

Implementation Notes:

Materials available to assist in meeting the Criterion

Policy (Pol 5A): Pharmacist Only Medicine Documentation

Tool 5A: List of Recordable Pharmacy Medicines & Pharmacist Only Medicines

Evidence Required for Assessment

- The Policy 'Pharmacist Only Medicine Documentation'
- Proof that the policy is being followed.
- Visual Proof that these purchases are being recorded for consumers with medication profiles.



Criterion 3 The pharmacy has a system for documenting inappropriate use of Pharmacist Only Medicines and Pharmacy Medicines where inappropriate use means either:

- Medicines being sought and/or taken for the wrong purpose;
- Consistent use of medicines which may indicate the presence of untreated medical conditions; and
- Medicines taken solely to support dependency.

Indicator

Required Actions & Behaviours:

- | | | |
|---|---|--------------------------|
| 1 | Develop and Maintain a list of items that may be subject to inappropriate use. | <input type="checkbox"/> |
| 2 | Confirm that all staff are aware of and have access to this list. | <input type="checkbox"/> |
| 3 | Develop and Maintain a system for documenting inappropriate use. | <input type="checkbox"/> |
| 4 | Confirm that all staff are aware of the system for documenting inappropriate use. | <input type="checkbox"/> |

Implementation Notes:

Materials available to assist in meeting the Criterion

Tool 5A: List of Recordable Pharmacy Medicine and Pharmacist Only Medicine

Evidence Required for Assessment

- A list of 'Recordable Pharmacy Medicine and Pharmacist Only Medicines'.
- Visual Proof that this list is utilised and up-to-date.

6. Rights and Needs of Consumers

Standard 6 All staff members respect the rights & needs of all consumers.

Criterion 1 Pharmacy staff:

- will provide respectful care at all times and under all circumstances,
- will handle information provided by consumers in a way that recognizes the privacy needs of the individual and protects the confidentiality of information, and
- are aware that the consumers have the right to refuse treatment or advice to seek alternative opinions.

Indicator

Required Actions & Behaviours:

- | | | |
|---|--|--------------------------|
| 1 | Develop and Maintain a written policy on the 'Rights and Needs of Consumers' | <input type="checkbox"/> |
| 2 | Confirm that all staff are aware of, and have access to, this policy. | <input type="checkbox"/> |

Implementation Notes:

Materials available to assist in meeting the Criterion

Policy (Pol 6A): Rights and Needs of Consumers

Evidence Required for Assessment

- The policy document 'Rights and Needs of Consumers'.
- Performance during a pseudo-patient visit.



Criterion 2 Consumers have access to a private consultation area within the pharmacy.

Indicator

Required Actions & Behaviours:

- 1 Provide an area in the pharmacy where private conversations cannot be overheard. (Note: This criterion may be achieved by ensuring that confidential conversations are conducted in such a way that they cannot be easily overheard.) ☐
- 2 Confirm that all staff members are of the requirements for conducting private conversations in the pharmacy. ☐

Implementation Notes:

Evidence Required for Assessment

- The area in the pharmacy where private conversations cannot be overheard.

Self assessment form and declaration

You can use this self-assessment form and declaration to assess your own practice.

Reasons why any indicators are marked Not Applicable

Action to be taken for any indicators currently not met or evidence unavailable

I have completed this assessment in a fair and ethical manner and fulfill the marked indicators in the supply of Pharmacy Medicines and Pharmacist Only Medicines.

(signed)

(date)



Policy 5A. POM Documentation

General Statement of the Policy

This pharmacy will keep records that ensure fulfilment of its legal and professional obligations and enable it to provide high quality and continuing care to its consumers.

Definitions

1. *Legal Obligations*

Include the responsibility to record all sales of Schedule 3 (recordable), and to ensure that *pharmacy* and *pharmacist only* medicines are not being used inappropriately.

2. *Consumers*

Include all consumers of the pharmacy, whether regular or casual.

3. *Records*

Include computer records, copies of communications with other professionals, and any other records that will enhance the provision of quality care.

4. *Continuing Care*

Refers to the need for pharmacies to have systems in place that enable staff who have a legitimate need to know, access to information that pertains to a consumer's care.

Application

1. The pharmacy will record sales of Schedule 3 (recordable) medicines in a format which is readily retrievable and accessible consistent with the provision of these Standards. Records will include the consumer's name and address, the quantity, strength and recommended dose of the product, and the condition for which the medicine is supplied.
2. Where possible, the pharmacy will record sales of *pharmacist only* medicines in the consumer's medication profile consistent with the provision of these Standards, and include the consumer's name and address, the quantity, strength and recommended dose of the product, and the condition for which the medicine is supplied.
3. The pharmacy will have a system by which the purchase of *Pharmacy* and *Pharmacist Only Medicines* that have been identified by the pharmacy as having potential for inappropriate use are monitored. Records of individuals who are suspected of inappropriate use will be kept and will be available to those persons who have a legitimate need to access.
4. Any additional record systems such as referral notes, reports and copies of information supplied will only be accessible to those persons who have a legitimate need to access.
5. All documentation will be kept and maintained in an orderly fashion.
6. Consumers have the right to request knowledge of what information is kept by the pharmacy regarding them. Pharmacies need to have a way of providing consumer access to such information that does not compromise the confidentiality of the records of other consumers. Consumers have a right to correct perceived inaccuracies in records concerning personal information.
7. This policy must be read in conjunction with the pharmacy's policy on respectful care.

Exceptions

While it is not legally necessary to record sales of *pharmacy* medicines, pharmacists carry a legal and professional responsibility for monitoring their use, with a view to promoting safe use and limiting inappropriate use. Therefore, requirements for recording these items may vary from time to time.

Responsibility

All pharmacists who work in the pharmacy, whether permanent or casual staff, carry responsibility for its application, and for taking appropriate remedial action when the policy is breached. Authority to provide information to consumers from records shall first be authorised by the senior pharmacist before release to ensure that confidentiality of other records is maintained.

Caveat

The provisions of this policy do not remove any responsibilities or rights to ensure compliance with State or Federal Acts regarding Privacy, Freedom of Information or any other relevant legislation.

Breaches of the Policy

Where breaches of the policy are identified, the senior pharmacist will take all reasonable steps to remedy it. These may, depending on the circumstance, include informing the consumer, making an appropriate apology, taking any steps to ensure future breaches do not occur, or any other reasonable action.

Note: This policy relates to:

Standard 5: Documentation

The pharmacy documents the provision of Pharmacist Only Medicines to ensure continuity of care and enhance optimal health outcomes.



Policy 6A. Rights and Needs of Consumers

General Statements of the Policy

Respectful care

This pharmacy respects the right for all individuals to receive respectful care and service.

Free choice

Consumers have a right to shared responsibility for their own health and wellbeing. This pharmacy will not compromise the ability of consumers to exercise free choice regarding health issues.

Privacy and confidentiality

Information provided to this pharmacy by consumers about an individual's health status or other personal matters will be treated as information to be held in trust, and will not be disclosed to persons who are not involved in providing continuing care without the express consent of the consumer involved, or where appropriate, the consent of the consumer's carer.

Definitions

1. *Information*

Refers to all forms of information whether written, spoken, electronically produced, or in any other form.

2. *Personal Matters*

Include:

- information about the individual's health status whether provided directly by consumers or their agents, or indirectly (for example, information deduced from medication use);
- information about medicines used, or about medication histories;
- information about personal relationships;
- information about disabilities;
- any other information that can reasonably be taken to be personal or sensitive.

3. *Disclosure*

Includes:

- the transfer of information to other professionals (eg. medical practitioners) and discussions with other staff members.

Applications

Respectful care

1. Staff members will not compromise service on the basis of gender, age, religion, ethnicity, sexual orientation or medical condition*.
2. Staff members will not speak or act towards any consumer in a way that will demean or embarrass them.
3. This pharmacy will endeavour to provide access to information for people whose first language is other than English. (Pharmacy Staff will be able to identify mechanisms for ensuring appropriate services and advice are provided to these consumers. These may include, among others, employment of staff who are fluent in languages found in the consumer base, accessing phone interpreter services, and developing agreements with other pharmacists who have relevant language capabilities).

4. Where barriers to communication are identified, this pharmacy will make every effort to reduce or remove them.
5. This pharmacy has a mechanism that allows consumers to offer feedback and opinion, as well as complaint and incorporates these data within its quality assurance framework.

* Although legal precedent does not exist relating to circumstances in which pharmacists' responsibilities under the respective State Poisons Regulations may conflict with the provisions of other Acts (eg. in the case of supply of restricted medicines to minors), these Standards have been drafted in the assumption that pharmacists must fulfil their responsibilities under the Poisons Regulations as a matter of priority.

Free choice

1. Consumers have the right to refuse treatment or advice and to seek alternative opinions. Pharmacy staff will present objective information and advice that enables consumers to make choices about their health.
2. Consumers will be treated courteously whether they accept or reject the advice given by pharmacy staff.

Privacy & confidentiality

1. When information is transmitted to a third party with the consent of persons or their carers, that person shall be provided with copies of the information.
2. Copies of any information transmitted will be filed in the pharmacy and available for access to the persons involved, their carers, or other professionals to provide continuity of care and for quality assurance purposes.
3. Written or other similar information will be disclosed in such a way that unauthorised persons cannot access it, and will only be available to staff who have a legitimate need to know in order to provide continuing care.
4. Conversations between staff members within the pharmacy concerning consumers' personal matters must be conducted in such a manner that they cannot be easily overheard by other consumers, and no conversations will be held in any public place regarding consumers' personal information.
5. Whenever information is transferred from one person to another it will always be done in a respectful manner, and only such information as is necessary to ensure effective and continuous care will be offered.

Duty of care

1. Pharmacists should always exercise their own clinical judgment and be mindful of their duty of care towards the consumer.

Exceptions

This policy does not apply in situations where:

1. The safety of the person would be compromised by not disclosing information (in which case the senior pharmacist should seek direction from appropriate agencies eg. the person's medical adviser, psychiatrist, psychiatric institution etc).
2. The safety of others would be compromised by not disclosing information (in which case, it is likely that both the police and those who are endangered may need to be notified).
3. Staff have knowledge of criminal activity (in which case the police need to be notified).



Responsibility for Application

Responsibility for the application of the policy rests with the senior pharmacist. In cases where doubt exists about how confidential materials should be handled, or whether confidential information should be recorded, or should be disclosed to others, non-pharmacist staff are required to report information to the senior pharmacist.

Pharmacists should always exercise their own clinical judgement and be mindful of their duty of care towards the consumer.

Breaches of the Policy

Where breaches of the policy are identified, the senior pharmacist will take all reasonable steps to remedy it. These may, depending on the circumstance, include informing the consumer, making an appropriate apology, taking any steps to ensure future breaches do not occur, or any other reasonable action.

Caveat

The provisions of this policy do not remove any responsibilities or rights to ensure compliance with State or Federal Acts regarding Discrimination, Privacy, Freedom of Information or any other relevant legislation.

Note: This policy relates to:

Standard 6: Rights and Needs

All staff members respect the rights & needs of all consumers.

Procedure 1A. Referring a Consumer to the Pharmacist

A. Purpose

To ensure that consumers who have been screened using the Procedure: Responding to Consumer Requests AND who require attention by the pharmacist are referred to the pharmacist in a timely fashion.

B. Scope

This procedure will be followed every time the Pharmacy Assistant determines that a consumer requires attention by the pharmacist.

C. Actions & responsibilities

1.1 *If the consumer has NON-URGENT needs, the pharmacy assistant will inform the pharmacist that a consumer requires their assistance.*

If the pharmacist is not involved with other tasks, the assistant will:

- introduce the pharmacist to the consumer in cases where they have not met.
- relate any information they have gathered during the consumer assessment procedure.
- Resume other normal duties, unless requested by the pharmacist or consumer to remain.

If the pharmacist is involved with other tasks, the assistant will:

- inform the pharmacist that a consumer requires their assistance.
- indicate to the consumer that the pharmacist is occupied with other tasks.
- negotiate with the pharmacist a time when the pharmacist will be available.
- inform the consumer of the expected time delay, and offer the consumer the opportunity to wait or return at a nominated time.
- ensure that the pharmacist is alerted regarding the nominated time if the consumer waits, or ensure that the pharmacist is informed when the consumer returns.
- resume normal duties, unless asked by the consumer or pharmacist to remain present.

1.2 *If the consumer has URGENT/EMERGENCY needs, the pharmacy assistant will:*

- immediately notify the pharmacist;
- alert other staff to attend to matters of security;
- remain available to the pharmacist for instructions.



D. Personnel involved

Pharmacist

Pharmacy Assistant

Consumer

E. Notes

This procedure relates to:

Standard 1: Resources

The pharmacy has adequate resources to consistently promote the quality use of Pharmacy Medicines and Pharmacist Only Medicines.

Criterion 3

There are adequate resources to allow consumers who require it to have timely access to a pharmacist for advice on the treatment of symptoms and the appropriate selection of Pharmacist Only Medicines, and where necessary, Pharmacy Medicines.

Procedure 4A. Responding to Consumer Requests

A. Purpose

To ensure that consumers (or their agents*) who request information on the treatment of symptoms, or requests/self-selects the purchase of a Pharmacist Only or Pharmacy Medicine, receive care and advice appropriate to their presentation and need.

* *Agents are third parties who request medicines or advice on behalf of another person.*

B. Scope

This procedure will be carried out every time a consumer (or their agent) enters the pharmacy and:

- Requests information on the treatment of symptoms OR
- Requests the purchase of a Pharmacist Only or Pharmacy Medicine

C. Actions & responsibilities

1.0 In response to such a request, the Pharmacy Assistant will:

- 1.1 **Engage** the consumer in conversation.
 - Use open-ended questions (questions that can't be answered by a Yes or a No) to involve the consumer in an informative two-way communication.
- 1.2 **Gather** appropriate and adequate information about the consumer's clinical status.
 - Interview the consumer using the pharmacy's standard protocol for Responding to Consumer Requests.
 - Assure themselves that this information is complete, current and accurate.
- 1.3 **Analyse** the information gathered during the assessment and determine the most appropriate action to take.
- 1.4 **Respond** to the request by taking the appropriate action. They will either:
 - complete the sale and/or provide appropriate information (if appropriately trained to do so);
 - refer the consumer to another pharmacy assistant (who is appropriately trained); OR
 - refer the consumer (or their agent) to the pharmacist (using the procedure for 'Referring a Consumer to a Pharmacist').

Notes:

In ALL instances where the Pharmacy Assistant has any doubt about their ability to correctly assess the consumer's clinical status or information request, they will refer the consumer to a Pharmacist. 'Appropriate information' should always include "follow-on information", ie, information on what to do next (eg. If symptoms do not improve, If you need more information).

2.0 In response to such a request, the Pharmacist will:

- 2.1 **Engage** the consumer in conversation.
 - Use open-ended questions (questions that can't be answered by a Yes or a No) to involve the consumer in an informative two-way communication.



- 2.2 **Gather** appropriate and adequate information about the consumer's clinical status.
- Assess any information provided by the pharmacy assistant.
 - Interview the consumer using the pharmacy's standard protocol for Responding to Consumer Requests.
 - Assure themselves that all information is complete, current and accurate.
- 2.3 **Analyse** the information gathered during the assessment and determine the most appropriate action to take.
- 2.4 **Respond** to the request by taking the appropriate action.
- 2.4.1 Facilitate the completion of the sale and/or provision of information. They will either:
- Authorise the pharmacy assistant to complete the sale and/or provide appropriate information to the consumer.
 - Provide appropriate information to the consumer and/or authorise the pharmacy assistant to complete the sale.
 - Complete the sale and/or provide appropriate information to the consumer themselves.
Note: 'Appropriate information' should always include "follow-on information", ie, information on what to do next (eg. If symptoms do not improve, If you need more information).
- 2.4.2 If appropriate, refer the consumer to another health care professional. If the consumer is identified by the pharmacist as needing the knowledge and skills of another professional for good care, the Pharmacist will:
- inform the consumer (or their agent) of the reasons for making a referral;
 - where appropriate, provide the consumer with a referral note, file a copy of the referral note, and record any other details as are needed for the provision of continuing care. (Referral Notes should be in triplicate (one copy for the consumer to give to the health care professional, one for the consumer to keep and one for the pharmacy records.))
 - where appropriate, follow-up to determine whether the consumer has acted upon the referral to another health care professional or has made a positive decision no to act.
- 3.0 **If the request is made by an agent (third party), pharmacy staff will:**
- 3.1 Follow the procedures outlined above and take all reasonable steps to ensure that the information provided by the third party is accurate.
- 3.2 Determine whether the third party has full responsibility for the consumer's medication (eg. parent of a child, or carer for an aged person). If they do not, the staff member will ensure that written information is always included with the medicine. This information should:
- provide advice on the safe and effective use of the product;
 - indicate what action to take if adverse effects are experienced;
 - provide information on how the consumer may contact a pharmacist for additional information.
- 4.0 **If Pharmacist Only or Pharmacy Medicines are supplied by post, the pharmacist will:**
- 4.1 Ensure that written information is always included with the medicine. This information should:
- provide advice on the safe and effective use of the product;
 - indicate what action to take if adverse effects are experienced;
 - provide information on how the consumer may contact a pharmacist for additional information.
- 4.2 Record details of the supply and the information provided.

D. Personnel involved

Pharmacist

Pharmacy Assistant

Consumer

E. Notes

This procedure relates to:

Standard 4: Consumers receive care and advice, appropriate to their presentation and need, that will facilitate the quality use of pharmacy medicines and pharmacist only medicines

Criterion 1

Systems are in place that assist pharmacy staff to:

- a. Engage consumers in conversation**
- b. Gather appropriate and adequate clinical information for each consumer who:**
 - **Presents with a symptom, or**
 - **Requests/Self-selects a Pharmacy Medicine or Pharmacist Only Medicine.**
- c. Analyse the information gathered and determine the most appropriate action to take.**
- d. Respond with appropriate care and advice.**



Tools

Tool 1A. Pharmacy Medicine and Pharmacist Only Medicine clinical reference list

Objective:

To list:

- All resource materials available in the pharmacy that can facilitate the appropriate provision of Pharmacy Medicines and Pharmacist Only Medicines.
- The location of these resource

STATE REQUIREMENTS			
Title	Author / Publisher	Version / Year of Publication	Location (bookshelf / internet address / CD etc)
ADDITIONAL RESOURCES			
Title	Author / Publisher	Version / Year of Publication	Location (bookshelf / internet address / CD etc)
IMPORTANT PHONE NUMBERS			
Poisons Information	Provider	Phone Number	
Drug Information Services			

Tool 1A. How to use the clinical reference list

Ensure that the list above is complete and current.

Ensure that the list is reviewed regularly, at least annually, and that all information is as up to date as possible.

REVIEW:

Name:	Signature:	Date:
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Name:	Signature:	Date:
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Tool 1B. Pharmacy Medicine and Pharmacist Only Medicine consumer reference list

Objective:

To:

- List all resource materials available in the pharmacy that can be PROVIDED TO CONSUMERS to facilitate the appropriate provision of Pharmacy Medicines and Pharmacist Only Medicines,
- Ensure currency of information
- Enable reordering of materials.

Tool 1B. How to use the consumer reference list

Ensure that the list above is complete and current.

Ensure that the list is reviewed regularly, at least annually, and that all information is as up to date as possible.

REVIEW:

Name:	Signature:	Date:
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Name:	Signature:	Date:
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Tool 2A. Competency list for pharmacists for supplying Pharmacy Medicines and Pharmacist Only Medicines

These competencies are sourced from the Competency Standards for Pharmacists in Australia 2003, Pharmaceutical Society of Australia, 2003.

These are the major competencies that are relevant to the supply of Pharmacy Medicines and Pharmacist Only Medicines.

Functional Area 1: Practise pharmacy in a professional and ethical manner

Competency Unit

- 1.1 Practise Legally
- 1.2 Practise to accepted standards
- 1.3 Pursue life-long professional learning and contribute to the development of others

Functional Area 3: Promote and contribute to the optimal use of medicines

Competency Unit

- 3.1 Participate in therapeutic decision-making
- 3.2 Provide ongoing pharmaceutical management
- 3.3 Promote rational drug use

Functional Area 6: Provide primary health care

Competency Unit

- 6.1 Assess primary health care needs
- 6.2 Address primary health care needs of patients
- 6.3 Promote good health in the community

Functional Area 7: Provide medicines & health information and education

Competency Unit

- 7.1 Retrieve information
- 7.2 Evaluate and synthesise information
- 7.3 Disseminate information

Functional Area 8: Plan & manage pharmacy resources

Competency Unit

- 8.3 Supervise staff
- 8.4 Work in partnership with others
- 8.5 Plan & manage pharmacy resources

Tool 2A. Competency list for pharmacy assistants for supplying Pharmacy Medicines

These competencies are sourced from the National Training Information Service website.
(<http://www.ntis.gov.au>)

These are the major competencies that are relevant to the supply of Pharmacy Medicines.

National Code	Unit of Competency Name
WRPCS101A	Meet and greet pharmacy customers
WRPMAR301A	Market and promote pharmacy products and services area
WRPPK201A	Apply product knowledge for analgesic and anti-inflammatory needs
WRPPK202A	Apply product knowledge for baby/infant care needs
WRPPK203A	Apply product knowledge for cough and cold needs
WRPPK204A	Apply product knowledge for diet and nutrition needs
WRPPK205A	Apply product knowledge for eye, ear and oral care needs
WRPPK206A	Apply product knowledge for gastro-intestinal needs
WRPPK207A	Apply product knowledge for home health care needs
WRPPK208A	Apply product knowledge for injury and wound care needs
WRPPK210A	Apply product knowledge for allergy conditions
WRPPK211A	Apply product knowledge for skin and fungal conditions
WRPPK214A	Apply product knowledge for women's and men's health needs
WRPPK316A	Provide health care advice, products and services on asthma needs
WRPPK317A	Provide health care advice, products and services on high blood pressure needs
WRPPK319A	Provide health care advice, products and services on diabetes needs
WRPPK320A	Provide health care advice, products and services on pregnancy and maternal health needs
WRPPK321A	Provide health care advice, products and services on smoking cessation needs
WRPPK322A	Provide health care advice, products and services on wound care needs
WRPPM301A	Co-ordinate pharmacy staff

Tool 2B. Training plan & record for training on Pharmacy Medicines & Pharmacist Only Medicines

Name:

Position:

[illegible]

* 'In-house' training on Pharmacy Standards, Policies, Procedures and Tools relating to Pharmacy Medicines and Pharmacist Only Medicines should be included in the plan. Consider various training providers, eg. PSA, Pharmacy Guild, ACP, AACP, Manufacturers, Marketing Groups, In-house training. *If desired, training records for the supply of Pharmacy Medicines and Pharmacist Only Medicines can be incorporated into a wider training plan.*

** A separate Training Summary Sheet must be completed for each training experience (Ref: TOOL 2C))

Tool 2B. How to use the training plan & record

Use this document to:

- PLAN training sessions that the staff member should attend / complete and
- RECORD attendance at training sessions.

Ensure that:

- the record of training completed is complete and current.
- for each training experience attended a Training Summary Sheet is completed and attached.
- the staff member has access to this document.
- the PLAN is reviewed regularly, at least annually, and that all information is as up to date as possible.

Review:

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Tool 2C. Training summary sheet



Name	Course Name	Course Date
The five key points I learnt from this training session were:		
1.		
2.		
3.		
4.		
5.		
Five things I will do in my day-to-day work as a result of this training:		
1.		
2.		
3.		
4.		
5.		

Tool 3A. Non-prescription medicines that may be subject to inappropriate use

Objective:

To:

- List all non-prescription medicines that may be subject to inappropriate use.
- Ensure currency of information
- Describe special instructions for dealing with these medicines

ITEM	DESCRIPTION (strength, pack size etc)	STORAGE REQUIREMENT	OTHER RELEVANT INFORMATION



How to use the list of items that may be subject to inappropriate use

Ensure that the list is complete and current.

Ensure that the list is reviewed regularly, at least annually, and that all information is as up to date as possible.

Review:

Name:	Signature:	Date:
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Tool 4A. Pharmacy Protocols

Protocols for the supply of Pharmacy Medicine and Pharmacist Only Medicines are designed to assist pharmacy staff to deliver appropriate and consistent professional service and advice to consumers who seek treatment for symptoms or self-medicate with Pharmacy Medicine and Pharmacist Only Medicines.

There are a range of protocols used in Australia. However, the essential aim of all protocols is the same: to ensure that pharmacy staff have gathered enough information to safely supply the most appropriate treatment for the consumer.

Rather than specify which protocols should be used in individual pharmacies, we have designed a form called Elements of a Protocol for Responding to Consumer Requests. This form outlines the essential elements of any protocol for the supply of Pharmacy Medicines and Pharmacist Only Medicines. These elements are also embedded in the Standards themselves, and in the Standard Operating Procedures for responding to consumer requests.

Essentially, pharmacy protocols should assist pharmacy Staff to:

- **ENGAGE consumers in conversation,**
- **GATHER appropriate and adequate clinical information from each consumer who**
 - o **Presents with a symptom, or**
 - o **Requests/Self-selects a Pharmacy Medicine or Pharmacist Only Medicine,**
- **ANALYSE the information gathered and determine the most appropriate action to take, and**
- **RESPOND with appropriate care and advice.**

Use this EGAR checklist to assess and perhaps modify the protocols you use in your pharmacy.

For reference, we have also included a copy of the most commonly used protocols in Australia, the WHAT STOP GO Protocol and the CARER protocol.

The WHAT STOP GO protocol has been rigorously tested in Australian pharmacies and includes the important first step of engaging the consumer in conversation. Importantly, if it is a Direct Product Request it encourages you to begin a conversation with the consumer by assessing consumer satisfaction with the product – using the question ‘How do you find this product.’



Tool 4A Elements of a protocol for responding to consumer requests

Does your Protocol include the Following Elements?

Does it assist staff to ENGAGE consumers in conversation?

For example:

For Direct Product Requests, staff could use the following opening questions:

How do you find this product? OR

How are you going with this product?

For Symptom Based Requests, staff could use the following opening question:

Tell me (more) about your symptoms?

Does it remind staff to GATHER clinical information during the conversation with the consumer?

For example, staff should determine:

Who is the patient?

What are the Symptoms? How long have they had them?

What Treatment/s have they tried for these symptoms? How effective were they?

Do they have any Other Medical Conditions?

Do they take any Other Medications?

Does it remind staff to ANALYSE the information they have gathered & determine which steps to take?

For example, staff should ask themselves:

Do I have enough information to safely supply an appropriate product and/or advice myself.

OR

Is there any reason for me to refer the consumer on:

Pharmacy assistants could refer the consumer to the pharmacist

Pharmacists could refer the consumer to another health care professional.

(see attached page: 'Examples of Reasons to Refer')

Does it assist staff to RESPOND appropriately?

For example:

Pharmacy assistants should either:

Refer the consumer to the pharmacist, OR

Supply a product and/or provide appropriate ADVICE.

Pharmacists should:

Refer the consumer to the another health care professional, AND/OR

Supply a product and/or provide appropriate ADVICE.

ADVICE should include:

Verbal Information on:

Product Use

Side Effects

Other Treatment Advice

Lifestyle Advice.

Written Information where appropriate.

Follow-On Information

Give the consumer information on what to do next, eg

If symptoms do not improve, If you need more information

Tool 4A. The protocols used in the pharmacy must clearly define when non-pharmacist staff should refer a consumer to a pharmacist.

Examples of reasons (triggers) for a pharmacy assistant to refer consumers to the pharmacist

Consumer-based triggers

- Age (under two years or elderly)
- Pregnant or breastfeeding
- Symptoms (not straightforward or persistent)
- Is taking other medication
- Has other medical conditions
- Appears to be under the influence of alcohol or drugs
- Looks unwell
- Unable to gather enough information
- Consumer requests pharmacist intervention

Staff-based triggers

- Do I know the best product to choose for this consumer? If not, refer.
- For DPRs: Is the requested product the right one for this consumer or is there a better alternative?
- For SBRS: Do I know which product is right for this consumer's symptoms?
- Do I have enough knowledge about this class of medicines or type of symptoms? If not, refer.
- Can I give the consumer the right advice on this product / their symptoms? If not, refer.
- Am I unsure whether to refer? If unsure, refer.

Product-based triggers

- Pharmacist Only Medicine
- Suspect Inappropriate Use
- Specific request by pharmacist for referral with this product.



Tool 4B.

Carer protocol for providing Pharmacy Medicines and Pharmacist Only Medicines	
Your pharmacy's protocols should indicate when the pharmacy assistant must refer to the pharmacist	
C	Check WHO is the patient? What are the symptoms? What has been tried? HOW LONG have the symptoms been present? Other MEDICATION? Other CONDITIONS?
A	Assess Diagnosis CLEAR? Medication therapy most APPROPRIATE? Possible INTERACTIONS? TRAINED and CONFIDENT?
R	Respond RECOMMEND appropriate therapy? REFER if uncertain, OR RECONSIDER if medication inappropriate
E	Explain VERBAL directions WRITTEN support WHAT TO DO if not improved REASONS for referral
R	Record IF LEGALLY REQUIRED Provide ONGOING CARE If REFERRED If MISUSE/ABUSE suspected

Tool 4B.



Tool 5A. List of recordable Pharmacy Medicine and Pharmacist Only Medicine

Objective:

To list:

- All PMs and POMs in the pharmacy that require documentation for supply
- The reasons for recording this information
- Instructions for recording this information.

Product Name/s	Reason for Recording (eg. Legislation / Potential for Inappropriate Use)	Instructions for Recording (eg. Dispensary Computer, Record Book etc)	Notes	Date



Tool 5A. How to use the list of recordable Pharmacy Medicine and Pharmacist Only Medicines

Ensure that the list above is complete and current.

Ensure that the list is reviewed regularly, at least annually, and that all information is as up to date as possible.

REVIEW:

Name: Signature: Date:

Name: Signature: Date:

Name: Signature: Date:

Name: Signature: Date:

Name: Signature: Date:



Glossary of Terms

Consumer

Health consumers include patients and potential patients, carers and organizations representing consumers interests.¹

Pharmacy Medicines (PM) (Schedule 2)

Pharmacy Medicines (S2) are substances or preparations for therapeutic use which are substantially safe in use but where advice or counselling is available if necessary, and are for minor ailments and symptoms which can be easily recognised by the consumer and do not require medical diagnosis or management.²

Pharmacist Only Medicines (POM) (Schedule 3)

Pharmacist Only (S3) Medicines are substances or preparations for therapeutic use which are substantially safe in use but require professional advice or counselling by a pharmacist; the use of which requires pharmacist advice, management or monitoring; and are for minor ailments and symptoms which can be identified by the consumer and verified by a pharmacist, and do not require medical diagnosis or only require initial medical diagnosis, and do not require close medical management.²

Standard

A benchmark that enables the interpretation of the significance of observed deviations of performance from the benchmark. In a risk management context, this enables a focus on identification, analysis, evaluation, intervention, monitoring and review of the observable and measurable aspects of performance.³ In the context of this document, a standard explicitly defines and describes the professional practice requirements of quality and effectiveness in relation to the provision of pharmacy medicines and pharmacist only medicines. As the standards outlined in this document are minimum standards each must be met in order to achieve the required level of practice.

Protocols

Outline the process to be followed by pharmacy staff when a *pharmacist only* or *pharmacy* medicine is supplied or advice on treatment of a medical condition is provided.

Direct Product Request (DPR)

Refers to a consumer's solicitation of a specific medicine upon entering the pharmacy.

Symptom Based Presentation (SBR)

Refers to a consumer's presentation with symptoms that require therapeutic advice.

Pharmacy Staff

Refers to all staff working in a pharmacy, including pharmacists, pharmacy assistants, and pharmacy technicians/dispensary technicians.

Pseudo-Patient Visit

Pseudo-patient visits are those in which a patient enters the health care setting, not to seek treatment, but to observe and/or test the health care process.⁴

References

- 1 Consumers' Health Forum of Australia, Information Brochure 2005.
- 2 Guidelines for National Drugs and Poisons Schedule Committee, Australian Health Ministers' Advisory Council, 1997.
- 3 AS/NZS Risk Management 4360:2004; Australian Council on Healthcare Standards, EQuIP, 3rd Edn Review 2005.
- 4 de Almeida Neto, AC, et al. Novel Educational Programs for Community Pharmacists. Am. J. Pharm. Educ. 64, 302-307, 2000.