Pharmaceutical Society of Australia

Dispensing Practice Guidelines

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Executive summary

Dispensing is a fundamental component of pharmacy practice, facilitating the safe provision of prescription medicines.

These guidelines provide information and guidance to assist pharmacists to meet their professional responsibilities, exercise professional judgement and manage risks associated with dispensing. They provide information and advice to pharmacists on professional issues related to dispensing.

The guidelines highlight contemporary considerations for pharmacists from the point of receiving a prescription, including:

- reviewing prescribed medicines effectively using the breadth of information sources available
- recording and documenting information to support decision making, taking into account the need to protect patient information
- selecting or accurately preparing the medicine
- labelling
- counselling.

These guidelines do not replace the need for pharmacists to exercise professional discretion and judgement when performing these tasks in their own practice environment. The guidelines do not include clinical information or detailed legislative requirements. Pharmacists must at all times comply with relevant Commonwealth, state and territory legislation, as well as relevant standards, codes and rules.

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About the guidelines

Purpose

The *Dispensing Practice Guidelines* describe the professional obligations of pharmacists when dispensing medicines.

These guidelines provide guidance on expected professional practice to provide optimal patient outcomes. This guidance includes (where relevant):

- appropriate and effective processes
- desired behaviour or minimum standards of good practice
- how duties and responsibilities may best be fulfilled.

The guidelines can be used as a tool to support balanced and professional decision making, and ensure that patients' needs, beliefs and preferences are met. They can be used as an educational resource to inform quality assurance processes, and to provide support when resolving legal disputes and ethical dilemmas.

Scope

These guidelines are applicable to all practice settings in which pharmacists dispense medicines, including non-prescription medicines. Some specialised dispensing activities (e.g. continued dispensing, Staged Supply, opioid substitution therapy) may also be covered by other guidelines.

Guidelines produced by the Pharmaceutical Society of Australia (PSA) are not definitive statements of correct procedure but represent agreement by experts in the field. The guidelines do not set a prescribed course of action or a mandatory standard to which pharmacists must adhere.

Pharmacists are expected to exercise professional judgement when adapting the guidance provided in these guidelines to specific circumstances.

The guidelines sit within a broader hierarchy of guidance underpinning and supporting the practice of pharmacists (see Figure 1).

Figure 1. Broad hierarchy of guidance and regulation of pharmacy practice

It is important to review these guidelines in conjunction with the:

- Pharmacy Board of Australia *Code of Conduct for Pharmacists*[1] and PSA *Code of Ethics*[2]
- relevant PSA *Professional Practice Standards*,[3] particularly Standard 3: Dispensing and Other Supply Arrangements
- Pharmacy Board of Australia *Guidelines for Dispensing of Medicines*[4]
- Pharmaceutical Defence Limited *Guide to Good Dispensing*[5]
- PSA *My Health Record Guidelines for Pharmacists.*[6]

Details of legislative requirements are not addressed in these guidelines. At all times, pharmacists must comply with relevant Commonwealth and state or territory legislation. No part of the guidelines should be interpreted as permitting a breach of the law or discouraging compliance with legal requirements.

Version history

VERSION	CHANGES
2017	Incorporated update to Pharmacy Board of Australia *Guidelines for Dispensing of Medicines* (2015) and PSA *Professional Practice Standards* (2017). Consolidated and superseded three separate guidelines: *Dispensing Practice Guidelines* (1999), *Guidelines for Pharmacists on PBS Brand Substitution* (2004) and *Consumer Medicine Information and the Pharmacist* (2007).
February 2019	Integrated pharmacist access to My Health Record following release of PSA ***My Health Record Guidelines for Pharmacists.*** Revised practice advice following Coroner's recommendation.*

* Pharmaceutical Defence Limited. Medication misadventure: methotrexate. 2018. At: https://www.pdl.org.au/members/Methotrexate (PDL member-only access)

Terminology

For some terms used in these guidelines, other terms with equivalent or similar meanings may be equally appropriate in certain contexts.

TERM	DEFINITION	EQUIVALENT OR RELATED TERM	SOURCE
Authorised representative	A person who can act on behalf of another person for the purposes of the My Health Record system, including viewing information, setting access controls and making registration decisions, as defined by the *My Health Records Act 2012*		7
Clinical incident	An event or circumstance that resulted, or could have resulted, in unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage. A clinical incident can be related to safety, usability, technical, privacy or security issues. For specific guidance on clinical incidents associated with the My Health Record system, refer to the latest version of the PSA *My Health Record Guidelines for Pharmacists*		6
Controlled drug	A medicine in Schedule 8 of the Standard for the Uniform *Scheduling of Medicines and Poisons* or designated as a Schedule 8 substance by state and territory regulation	Schedule 8 medicine, Schedule 8 poison	8
Counselling	A two-way communication process between the pharmacist and the patient in which the pharmacist ascertains the needs of the patient, and provides them with the information required to safely and effectively use medicines and therapeutic devices	Communication with patients or carers	3
Dispensary assistant/technician	A suitably trained individual who assists a pharmacist in the preparation, dispensing and supply of medicines, and other tasks in a pharmacy business or pharmacy department		4
Dispensing	The review of a prescription, and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine. It includes counselling of a patient, their agent or another person who is responsible for the administration of the medicine to that patient		4
Health literacy	Skills, knowledge, motivation and capacity of a person to access, understand, appraise and apply information to make effective decisions about health and health care, and take appropriate action		6
Healthcare Provider Identifier—Individual (HPI-I)	A unique 16-digit number used to identify individual healthcare providers who deliver health care in the Australian setting		9
Healthcare Provider Identifier—Organisation (HPI-O)	A unique 16-digit number used to identify organisations that deliver health care in the Australian setting		9
Individual Healthcare Identifier (IHI)	A unique 16-digit number used to identify individuals who receive or may receive health care in the Australian health system		9
Medication-related problem	An event or circumstance involving drug treatment that actually or potentially interferes with the patient experiencing an optimum outcome of medical care	Adherence issue, adverse drug event, adverse drug reaction, drug-related problem, medication error	10
My Health Record	An online summary of an individual's key health information, controlled by the consumer and maintained by the Australian Digital Health Agency as System Operator	Digital health record, e-health record, personally controlled electronic health record (PCEHR)	11
My Health Record system	The infrastructure and operational support for delivering My Health Records		11

TERM	DEFINITION	EQUIVALENT OR RELATED TERM	SOURCE
Non-pharmacist staff	All pharmacy staff excluding provisionally or generally registered pharmacists		
Patient	A person who uses, or is a potential user of, health services, including their family, carer(s) or agent	Consumer, healthcare recipient, client	12
Patient healthcare record	A record of information in the dispensing software relevant to the patient's health, including clinical history, clinical findings, investigations, information given to the patient, their medication and other management	Dispensing record, medication profile, medication record, patient profile, patient record	4
Patient identifiers	Items of information accepted for use in patient identification, including patient name (family and given names), date of birth, gender and address. Specific patient identifiers allow matching of a patient's record in dispensing software with a patient's Individual Healthcare Identifier (IHI) in the My Health Record system		13
Pharmacist Only medicines	Substances whose safe use requires professional advice but that should be available to the public from a pharmacist without a prescription	Schedule 3 medicines, Schedule 3 poisons	8
Prescriber	A health professional authorised to undertake prescribing within the scope of their practice	Doctor, dentist, general practitioner (GP), nurse practitioner, optometrist, other approved non-medical prescriber, specialist, veterinarian	14
Sensitive information	Any type of personal information that, if disclosed or handled inappropriately, can leave an individual vulnerable to discrimination, mistreatment, humiliation or embarrassment. For example, it may encompass any information that defines or infers race or ethnic origin; political opinions; religious beliefs and affiliations; philosophical beliefs; sexual preferences and orientation; criminal record; or health, genetic or biometric information		15
Supply of medicines	The act of providing medicines to a person or third party for use by the person only		14
System Operator	The participant with responsibility for establishing and operating the My Health Record system. The System Operator is currently the Australian Digital Health Agency		9
Therapeutic good	In relation to evaluation, assessment and monitoring by the Therapeutic Goods Administration, therapeutic goods are broadly defined as products for use in humans in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; influencing, inhibiting or modifying a physiological process; testing the susceptibility of people to a disease or ailment; influencing, controlling or preventing conception; or testing for pregnancy. They include things that are used as an ingredient or component in the manufacture of therapeutic goods, or to replace or modify parts of the anatomy		16

Introduction

Dispensing is a fundamental component of pharmacy practice,[17] facilitating the safe provision of prescription medicines and devices as part of the medication management pathway.[18]

Dispensing includes all the activities that occur between the time the prescription is presented in a pharmacy and the time the medicine is supplied to the patient.[19] It involves "the review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counselling to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient".[4]

Separation of dispensing from prescribing facilitates an independent review of a prescription before the patient begins treatment.[20] When dispensing, a pharmacist must make the health and wellbeing of the patient their first priority, and demonstrate responsibility and accountability for all decisions made and actions taken.[1]

Dispensing should reflect and uphold the principles of quality use of medicines (QUM). QUM involves[21]:

- selecting health management options wisely by considering the place of medicines in treating illness and maintaining health
- choosing suitable medicines, if a medicine is considered necessary
- using medicines safely and effectively to achieve the best possible results.

The dispensing process

When dispensing medicines, pharmacists should ensure that[4]:

- the prescription is valid, according to relevant legislation
- the patient's identity is confirmed and recorded accurately in the dispensing software
- the medicine is clinically appropriate for the patient
- information is provided to ensure safe and appropriate use of the medicine.

Throughout the dispensing process, pharmacists have a responsibility to:

- apply their expertise
- use professional judgement to protect and promote the safety, health and wellbeing of patients
- protect patient privacy and confidentiality, including the handling of sensitive information
- maximise therapeutic outcomes, in partnership with patients and prescribers.

Dispensing activities should be guided by a standard operating procedure that outlines the[3]:

- steps involved in the dispensing process (see Figure 2)
- responsibilities of pharmacy staff members in the dispensing process
- training plan for staff involved in the dispensing process
- risk management plan (see Box 4).

Figure 2. The dispensing process

The dispensing process

Step 1

Receiving a prescription

Ascertain authority to prescribe and validity of prescription

Step 2

Reviewing prescribed medicines

- Correctly identify the patient and obtain supplementary information
- Determine the prescriber's intentions, including the dosing instruction
- Review the medication history
- Obtain relevant patient information from other sources, including state/national digital platforms

Step 3

Considering supply arrangements

- Make decision to supply or decline supply
- Comply with legal and professional obligations for specific supply arrangements (e.g. scheduling of medicines, PBS-subsidised or emergency supply)

Step 4

Communicating with the prescriber, as required

Collaborate with the prescriber to ensure medicine safety

Step 5

Recording and documentation

- Input prescription data accurately into dispensing software
- Document medicine-related problems where appropriate

Step 6

Selecting or preparing the medicine

- Select or prepare the medicine
- Use a barcode scanner if packaging includes a barcode

Step 7

Labelling

- Label the medicine
- Use cautionary advisory labels where appropriate

Step 8

Supplying and counselling

- Check and recheck all dispensing for accuracy and completeness
- Confirm patient identity
- Counsel the patient, where appropriate

Step 9

Following up with patient or prescriber as required

Reference: Adapted from Pharmacy Board of Australia[4]

Reviewing prescribed medicines

The pharmacist has a professional responsibility to review medicines prescribed for patients to ensure that they reflect the prescriber's intentions, and are consistent with QUM and the patient's health goals and values.[3] This review should be undertaken in collaboration with the patient.

The review of prescribed medicines should consider[4,17]:

- the suitability of the medicine with regard to indication, adverse drug reactions and contraindications
- the suitability of the dosage regimen, including dose, frequency, route of administration and duration of treatment
- any dosage change
- any potential interactions
- the patient's adherence to the prescribed regimen (e.g. overuse or underuse of medicines).

Correctly identifying the patient

The pharmacist should be satisfied that the medicine that is being dispensed is for the person for whom it was intended.[4] Information that enables correct patient identification includes:

- surname
- given name(s)
- date of birth
- gender
- address
- Medicare card number or DVA number.

The pharmacist should ensure that patient identity is confirmed by collecting patient identifiers and recording them in the dispensing software before dispensing, and again before supplying the medicine to the patient and counselling.

Patient identifiers may be considered sensitive information by the patient. The pharmacist should make genuine efforts to understand the cultural needs and contexts of different patients, and modify their approach accordingly.[4]

While respecting individual choice, the pharmacist may wish to consider making the patient aware of the risks associated with not disclosing identifiers, and ensure that any action is consistent with patient safety.

Specific patient identifiers are required for some supply arrangements (e.g. subsidisation under the Pharmaceutical Benefits Scheme [PBS], supply of controlled drugs under state or territory legislation).

The My Health Record system uses specific patient identifiers for validating a patient's Individual Healthcare Identifier (IHI) and linking the patient's record in the dispensing software (see Box 1).

Box 1. Patient identifiers for the My Health Record system

- Surname
- Given name(s)
- Date of birth
- Gender
- Medicare card number or DVA number

Pharmacy workflows must ensure that patient information, including date of birth and gender, is captured in the dispensing software to enable the upload of dispensing information to the patient's My Health Record.

Obtaining relevant patient information

The pharmacist has a professional obligation to ensure that they have sufficient patient information to review the medicines prescribed. Reviewing medicines may involve[6]:

- assisting with reconciliation of patient medicines to produce an accurate medication profile
- accessing patient information, including allergies, adverse reactions and non-prescription medicines
- accessing clinical information, such as discharge summaries, medication summaries and pathology results, in a timely manner
- enhancing continuity of care between different healthcare settings
- confirming appropriateness of treatment based on medical history
- accessing immunisation records and child health check summaries.

The pharmacist should make reasonable attempts to access information required to inform clinical decisions.

Sources of information include:

- patient or agent
- prescriber
- members of the healthcare team
- pharmacy/facility records
- My Health Record
- medicine monitoring systems.

It is important that pharmacists recognise that these are only some of the potential sources of patient health information and should not be assumed to provide a complete record. The pharmacist should consider the need to consult additional sources of information in addition to, or instead of, these sources, based on the episode of care being provided.

Patient, prescriber and members of the healthcare team

Communication and collaboration with the patient, prescriber and members of the healthcare team will be a primary source of relevant patient information.

Pharmacy/facility records

Pharmacies, and the facilities to which they provide services, hold a broad range of records that can be a source of patient information. These may be held in different software programs or in hard-copy (paper-based) records. They include:

- dispensing history
- patient history (clinical) notes
- records of clinical interventions (electronic or paper-based systems)
- controlled drug registers
- compounding (extemporaneous dispensing) records
- medication charts in aged care facilities and hospitals
- profiles and packing records for dose administration aids
- hospital patient records.

My Health Record system

The My Health Record system provides the pharmacist with an accessible source of information that may help them to meet professional obligations, and provide safe and appropriate patient care. The pharmacist should only view a patient's My Health Record when they reasonably believe that this will assist them to provide better patient care.

The My Health Record system has been designed to enable the patient to control the content of their record, and who can access their information. Pharmacists should acknowledge the right of patients to control access to information in their My Health Record and discuss why they need access to information if access has been restricted.[6]

Pharmacists can use the emergency access functionality to bypass the existing access controls in certain emergency situations.[7] If a patient's My Health Record is accessed under these circumstances, details of the access should be recorded in the patient's healthcare record in the dispensing software. The System Operator monitors use of the emergency access functionality and can request more information about the circumstances relating to its use.

For more detail about patient information included in the My Health Record system, and the pharmacist's obligations and opportunities for integrating use of the system in patient care, see the latest version of the Pharmaceutical Society of Australia (PSA) *My Health Record Guidelines for Pharmacists*.[6]

Medicine monitoring systems

Real-time prescription monitoring systems (to date, these include DORA in Tasmania, SafeScript in Victoria, and the Electronic Recording and Reporting of Controlled Drugs system being pursued nationally) may also be available to provide the pharmacist with information about medicines that have a high risk of harm, supporting the pharmacist's review of the medicines prescribed.

Other medicine monitoring systems and services exist for specific medicines:

- Monitoring systems are required for the use of clozapine because of its significant adverse effect profile, such as agranulocytosis.[22]
- Project STOP provides a database to track pseudoephedrine sales in real time, because of its use in the manufacture of methamphetamine.[23]

These medicine monitoring systems currently operate independently of dispensing software and the My Health Record system, and need to be accessed separately.[24] Use may be subject to state or territory legislation.

Considering supply arrangements

Pharmacists must comply with relevant Commonwealth, state or territory legislation associated with the dispensing and supply of medicines. They must carefully consider and confirm their obligations if they are not familiar with a specific supply arrangement.

Scheduling of medicines

Medicines are classified into schedules according to the level of regulatory control over their availability. These are recorded in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).[8]

Pharmacists must comply with the legislative controls imposed by state and territory governments, which generally, but not always, flow from the schedule in which the medicine is included.

Controlled drugs

The dispensing of controlled drugs (also known as Schedule 8 medicines) is governed by additional Commonwealth, state or territory rules or requirements. Pharmacists must refer to the relevant legislation for information about the legal requirements for dispensing these medicines (e.g. repeat dispensing intervals).

Pharmacists should contact the prescriber to confirm the validity of the prescription for a controlled drug if it has been altered, or has been written by a prescriber not known to the pharmacist.

Emergency supply

All state and territory legislation has provisions for pharmacists to dispense an emergency supply of most medicines in the following circumstances:

- There is an immediate need to supply the medicine to continue current essential medical treatment.
- The medicine has been previously prescribed to a person (not an animal).
- It is impracticable to obtain a valid prescription.

Pharmacists should refer to specific state or territory legislation for the relevant requirements.

In these circumstances, the pharmacist may supply up to 3 or 7 days treatment of the medicine (depending on the state or territory) without a prescription from a medical practitioner.

For a pre-packed liquid preparation, cream, ointment or pressurised aerosol container, or an anovulant (oral contraceptive), the smallest standard pack may be supplied.

Emergency supply provisions cannot be used for controlled drugs or, in some jurisdictions, anabolic steroids, benzodiazepines or barbiturates.

An emergency supply of a medicine cannot be dispensed as an owing prescription or as a PBS-subsidised prescription.

PBS-subsidised supply

Medicines are most commonly subsidised through the PBS or the Repatriation Pharmaceutical Benefits Scheme (RPBS). Pharmacists supplying PBS-subsidised medicines must comply with the requirements set out in the relevant Commonwealth legislation.[25,26]

PBS brand substitution

Pharmacists may substitute an 'a'-flagged PBS medicine with a bioequivalent (generic) or biosimilar medicine without reference to the prescriber. Before substituting medicines, the pharmacist must obtain patient consent and confirm on the prescription that the prescriber has not prohibited substitution (see Appendix 1).

Early supply of repeats

Under the PBS, pharmacists are permitted to dispense a prescription as an early repeat supply (i.e. the minimum required interval between supplies has not been met) if the patient's PBS medicine has been lost, stolen or destroyed, or the medicine is required without delay for treatment. The pharmacist must be satisfied that one of these conditions is met. The pharmacist must sign the prescription and annotate it with "immediate supply necessary". The pharmacist would be expected to note the reason for the immediate supply in the patient's record in the dispensing software.

Dispensing multiple repeats at one time

Pharmacists must ensure that the supply of dispensed medicines is consistent with the prescriber's intentions, QUM and the pharmacist's clinical judgement. The prescriber determines appropriate therapy and communicates this to the pharmacist via details on the prescription, including the quantity to be supplied and the number of (and interval between) repeats. This means that each repeat must be supplied on a separate occasion, allowing review of therapy, if necessary, based on the patient's response, and minimising the risk of medication misadventure or use of unnecessary medicines.

If the PBS listing and arrangements do not meet the medication needs of the patient, the prescriber may:

- provide for larger quantities and/or repeats through a PBS Authority prescription
- endorse the PBS or RPBS prescription to authorise the pharmacist to dispense the original and all repeats at the same time, as permitted under regulation 49 of the National Health (Pharmaceutical Benefits) Regulations 2017, and annotate the prescription "Regulation 24")[#]
- prescribe the quantity and number of repeats needed on a private prescription.

In addition, there may also be circumstances when simultaneous supply of multiple quantities of a medicine is genuinely in the best interests of the patient to ensure continuity of therapy (e.g. the patient's travel schedule does not permit repeat prescriptions to be obtained in a timely manner).

Previously regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960

If a medicine is dispensed early or multiple repeats are dispensed at one time, pharmacists should include detailed notes in the patient healthcare record.

State and territory legislation may impose additional restrictions on early dispensing or the dispensing of multiple repeats, and on multiple supply without appropriate clinical or practical need. Pharmacists should ensure that they adhere to all legislative requirements.

Urgent cases

In urgent cases, pharmacists can supply a PBS-subsidised medicine without a prescription, provided that details of the prescription are given by the prescriber via telephone, fax or electronic means. The written PBS prescription must be forwarded by the prescriber to the pharmacist within 7 days of the supply.

Eligible medicines ('statins' and oral hormonal contraceptives) may also be supplied without a prescription by continued dispensing. This may be appropriate if the medicine was supplied to the patient in the past 6 months and their condition is stable, and the medicine was not supplied by any pharmacy as a continued dispensing medicine in the past 12 months.[27]

Alternative and extended subsidisation arrangements

A number of medicines are available as pharmaceutical benefits under alternative or extended arrangements to PBS arrangements. These include:

- section 100 items (e.g. highly specialised drugs, chemotherapy, botulinum toxin, growth hormone, in vitro fertilisation treatment, opiate dependence treatment)
- medicines for eligible Aboriginal and Torres Strait Islanders living with, or at risk of, chronic disease.

For more information, refer to Appendix 2.

Indirect dispensing

Indirect dispensing is the supply of medicines when there is no face-to-face contact between the patient and the dispensing pharmacist. This includes supply of prescription medicines and scheduled products after contact with the patient via telephone or email.

The dispensing pharmacist must comply with all relevant legislation and Pharmacy Board of Australia guidelines when supplying medicines in this manner.[4]

Delivery of prescription medicines or scheduled items by mail or other courier services is not encouraged, except in cases of clear need.

When medicines are supplied by indirect dispensing, the pharmacist should fulfil all appropriate professional requirements to ensure the safe and correct use of the medicine, and to exercise proper and reasonable care.[4] The pharmacist must ensure that sufficient information is provided in relation to indications, dosage and possible adverse reactions to enable patients to make informed decisions.

All functions performed by either pharmacists or dispensary assistants/technicians must be described in standard operating procedures. The premises from which a mail-order dispensing service takes place must comply with all the regulatory requirements relating to the practice of pharmacy.

Supporting medicine administration

Pharmacists may use a number of supply arrangements to assist in the safe and effective administration of a patient's medicines, and to enhance adherence. These include:

- dose administration aids (e.g. to a residential aged care facility)
- imprest stock (e.g. to a hospital ward)
- supervised supply (e.g. opioid substitution therapy)
- restricted supply or Staged Supply (e.g. supply of medicine in periodic instalments, each containing less than the originally prescribed quantity).

Supply arrangements should be in accordance with state and territory regulations, the Pharmacy Board of Australia *Guidelines on Dose Administration Aids and Staged Supply of Dispensed Medicines*[28] and the PSA *Professional Practice Standards*.[3]

Accessing unapproved medicines

Medicines are usually only prescribed if they have been approved by the Therapeutic Goods Administration for inclusion in the Australian Register of Therapeutic Goods.

Unapproved medicines can be obtained through[29]:

- the Special Access Scheme, where the import and/or supply of an unapproved therapeutic good for a single patient is arranged on a case-by-case basis
- the Authorised Prescriber Scheme, where medical practitioners can be granted authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients
- importation for personal use
- clinical trials.

For more information, refer to Appendix 2.

Declining to supply

Pharmacists should exercise professional autonomy, objectivity and independence in the dispensing process.[2] They have the right to decline to supply medicines if they believe use is unsafe or inappropriate, even if the prescriber is not in agreement.

While respecting the autonomy of the patient and the prescriber, the pharmacist must ensure that the patient is adequately informed about:

- the reasons for declining to supply the medicine, including the benefits and risks associated with the medication-related problem (MRP) that has been identified
- recommended action to be taken by the patient to pursue safe and appropriate treatment in a timely manner; the patient should be provided with information to support further discussion with the prescriber, if required.

Information should be provided verbally and in writing to the patient. It should be provided in a manner that maintains the patient's confidence in their prescriber and does not cause them unnecessary alarm.

The justifications for declining to supply a medicine and recommended action to be taken by the patient should be recorded in the patient healthcare record in the dispensing software.

Communicating with prescribers

Pharmacists should collaborate with the prescriber to ensure safe and effective supply and use of medicines.[3] This may occur at any point in the dispensing process.

Contact with the prescriber may be required if there is[17]:

- doubt about the legality or validity of the prescription
- uncertainty about the prescriber's intention
- clear potential for drug misadventure
- apparent overuse or underuse of a medication
- doubt about the suitability of the medicine for the patient.

Pharmacists should communicate the need to discuss concerns or a need for clarification with the patient before contacting the prescriber. When communicating with a prescriber or other health professional about an MRP, the pharmacist should specify their particular concern, provide supporting evidence and suggest appropriate alternatives.

The pharmacist must be satisfied as to the safety of the medicine for the patient before the medicine is dispensed. They must make the health and wellbeing of the patient their first priority, and demonstrate responsibility and accountability for all decisions made and actions taken.[1]

If the prescriber is not in agreement with the pharmacist's concerns, pharmacists should also consider the patient's therapeutic need while safety is being ascertained. As well as having the right to decline to supply medicines if they believe use is unsafe or inappropriate, pharmacists may consider alternative options such as suspending of supply, provision of a reduced quantity or increased monitoring.

Where the pharmacist has declined supply of a medicine, verbal communication with the prescriber should be followed up with written information sent to the prescriber about the action taken, for their records. Information should be communicated effectively, respectfully and in a timely manner to support effective decision making. Communication should demonstrate an understanding of each other's roles, responsibilities, capacities and constraints in the care of the patient.

Outcomes of communication with prescribers should be documented in the patient healthcare record within the dispensing software, where relevant.

Non-medical prescribers

Non-medical prescribers (e.g. optometrists, nurse practitioners, podiatrists, veterinarians) have limited prescribing rights in some states and territories. Non-medical prescribers must only prescribe within their scope of practice. Pharmacists should satisfy themselves that prescriptions written by all prescribers, including non-medical prescribers, are written in accordance with relevant regulatory (including legislative) requirements.

Recording and documentation

The patient healthcare record should be created or updated in the pharmacy dispensing software at the time of dispensing, and the information confirmed as correct. Recording information gathered during the dispensing process will enhance the quality and integrity of all professional services provided by the pharmacy.

At the time of dispensing, the pharmacy dispensing software is used to:

- record the details of all prescriptions dispensed
- record any other legally required details of dispensing
- generate a dispensing label
- generate a repeat authorisation to attach to the duplicate of the prescription (if required).

The electronic record of supply of a medicine to a patient should accurately record the pharmacist who is taking responsibility for dispensing the medicine. National electronic prescription will be implemented in the near future, and this makes accurate recording of the responsible pharmacist in the dispensing software even more crucial.

The patient healthcare record may include:

- patient details (e.g. date of birth)
- medical history, including details of medical conditions, allergies and adverse reactions
- details of medicines the patient has been dispensed, including non-prescription medicines and complementary medicines
- details of any recent medication changes
- relevant patient notes, including brand preferences, details of services provided, communication with the prescriber, reasons for early or multiple repeats supplied, and follow-up actions required.

Maintaining patient privacy

Patient information collected and recorded during the dispensing process is confidential. It should only be used for the purpose for which it was collected (other than for exceptions allowed by the *Privacy Act 1988*[9]). The Australian Privacy Principles[10] give legislative force to Care Principle 2 of the PSA *Code of Ethics for Pharmacists*[2] regarding confidentiality of information.

Patient information should only be used and disclosed with the patient's consent, unless required by law.[30] Patient consent is required before patient information is disclosed to a carer, agent or authorised representative collecting a medicine on behalf of the patient.

If the patient is unable to consent to the disclosure of their information, the pharmacist may disclose information to another healthcare professional treating the patient, or another responsible person, provided that the pharmacist is satisfied that the disclosure[30]:

- is reasonable and necessary to provide appropriate care or treatment, or is made for compassionate reasons
- is not contrary to any patient wishes about disclosing health information the pharmacist knows, or should know.

If the patient does not consent to the disclosure of information that the pharmacist believes is in the best interests of that patient, the pharmacist should make the patient aware of the risks associated with the information not being disclosed and ensure that any action is consistent with patient safety.[30]

Documenting medication-related problems

The pharmacist should document details of any MRPs identified during the dispensing process and clinical interventions performed. Examples of MRPs that may be identified are[10]:

- potential overuse or duplication of medicines, or overtreatment of conditions
- a medical condition (e.g. poorly controlled hypertension) that may require enhanced therapy or improved medication adherence
- a need for preventive therapy, such as adequate intake of calcium and vitamin D in a consumer with osteoporosis
- in dispensing a repeat prescription from another pharmacy, identification that it had been previously dispensed incorrectly
- a request from a patient for further information regarding the medicine or disease management
- justifications for declining to supply a medicine and recommended action to be taken by the patient.

Outcomes of any communication with the prescriber or patient should be documented in the patient healthcare record, where relevant.

Patients have a right to gain access to all information the pharmacy holds about them.[31] Pharmacists should be cognisant of the potential for patients and other health professionals to view records when documenting details in the dispensing software or a patient's My Health Record.

For more detailed information about performing and documenting MRPs and clinical interventions, see the PSA *Guidelines for Pharmacists Performing Clinical Interventions*.[10]

Contributing to the My Health Record system

The pharmacist can upload dispensing information directly to a patient's My Health Record if [6]:

- the pharmacy is using conformant dispensing software
- the prescription is dispensed using the credentials of an authorised user (e.g. a pharmacist with a Healthcare Provider Identifier—Individual [HPI-I] and granted access by their pharmacy with a Healthcare Provider Identifier—Organisation [HPI-O])
- the relevant IHI for the patient receiving the prescribed medicine has been validated
- the patient has a My Health Record and has not withdrawn consent.

To enable dispensing information to be uploaded accurately, the pharmacist should ensure that the correct patient is selected in their dispensing software at the time of dispensing. All patient identifiers must be confirmed and recorded for the patient's IHI to be validated and matched with the correct record in the My Health Record system.

Under the *My Health Records Act 2012*, pharmacists directly involved in the patient's care can upload information to their record. The pharmacist does not need to obtain express or written consent, except where state or territory law requires it (e.g. certain types of sensitive information).[32]

Sensitive information

Sensitive information is any type of personal information that, if disclosed or handled inappropriately, can leave the individual vulnerable to discrimination, mistreatment, humiliation or embarrassment.

For example, it may encompass any information that defines or infers race or ethnic origin; political opinions; religious beliefs and affiliations; philosophical beliefs; sexual preferences and orientation; criminal record; or health, genetic or biometric information.[15]

Legislation in some states and territories prevents the disclosure of certain sensitive information unless express or written consent is provided.[32] Uploading such information to a patient's My Health Record would be considered disclosure. State- and territory-specific information is given in Appendix 3.

Pharmacists should exercise professional judgement before uploading any potentially sensitive information. For example, information about psychotropic medicines, antimicrobials for sexually transmissible infections or medicines for sexual dysfunction may be considered as 'sensitive' by an individual patient.

Regardless of consent requirements, it is good practice for pharmacists to advise patients when information is being uploaded to their My Health Record (e.g. by using communication tools indicating the pharmacy's use of the My Health Record system), and to proactively discuss potentially sensitive information with the patient so that the patient can make an informed decision.

When consent is withdrawn

The default setting for most pharmacy software is to upload all patient dispense records. If a patient has advised that they do not consent to having their dispense record uploaded to their My Health Record, pharmacists should refer to their software manual or contact the software vendor for information on how to prevent dispense records from being uploaded (as the step required differs slightly for each type of software).[24] PBS information will continue to be uploaded to the patient's My Health Record. Should the patient wish to change this preference, they can do so themselves through the consumer portal of the My Health Record system.[33]

Upload errors

If dispensing information has been uploaded in error or contains a mistake, a pharmacist can edit the information in the pharmacy's dispensing software. The edited version is then uploaded and supersedes the original. Dispensing information that has been deleted from the pharmacy's dispensing software will not display in a patient's My Health Record.

For more detailed information about patient consent in accessing the My Health Record system, the pharmacist's obligations and opportunities for integrating use of the system in patient care, and how to respond to errors identified in a patient's My Health Record, see the latest version of the PSA *My Health Record Guidelines for Pharmacists*.[6]

Recording *Pharmacist Only* medicines

The pharmacist should record the supply of *Pharmacist Only* medicines in accordance with relevant state or territory legislation. If recorded in conformant dispensing software, this dispensing will be uploaded to the patient's My Health Record, providing a more complete record of medicines dispensed for the patient and healthcare providers.

Security and access to patient information

A pharmacist must take reasonable steps to ensure that patient information is protected, and not subject to misuse, interference, loss, unauthorised access, modification or disclosure.[4,6] This applies to patient information held electronically or in hard-copy (paper-based) records. It also includes printed documentation such as labels, repeat forms, claim forms and receipts.

Paper-based records should be stored securely, and staff access should be restricted to when there is a health or reasonable operational need. Personal information should be destroyed or de-identified when it is no longer required to be retained by the pharmacy.[30]

For electronic records, pharmacists should:

- maintain a robust password for accessing software that holds patient information
- change the password regularly
- implement a robust process for sharing the password with dispensary assistants/technicians and interns
- close patient records after use.

Third-party providers (including cloud computing)

Where part or all of the handling of personal information (collection, processing or storage) is outsourced to third-party providers (including cloud computing, and systems such as GuildCare and MedAdvisor), pharmacists must ensure that the terms of the contract enable them to meet their obligations under the Privacy Act and that there is minimal risk in relation to the protection of personal information.[34]

Access to the My Health Record system

Under the *My Heath Record Rule 2016*, pharmacies must develop and maintain a robust security and access policy.[35] The policy should outline access procedures, staff training and security measures used by the pharmacy. The Responsible Officer for the pharmacy organisation (e.g. pharmacy owner, pharmacist manager) has responsibility for reviewing, updating, maintaining and enforcing the policy, and promoting it to staff.[6]

A pharmacist's responsibility is to ensure that staff who access the My Health Record system are directly supervised, and have appropriate training and experience, in accordance with the pharmacy's My Health Record Security and Access Policy.[6]

Access to the My Health Record system can be gained through conformant dispensing software. Non-pharmacist staff may access the My Health Record system only if the pharmacist delegates them access, as defined in the pharmacy's My Health Record Security and Access Policy. The pharmacist is responsible for access to the My Health Record system by non-pharmacist staff that occurs under their delegation.[6]

Intern pharmacists have access to the My Health Record system under their own HPI-I. However, the supervising pharmacist still has responsibility for activities undertaken by intern pharmacists, and is expected to supervise and monitor their access to the My Health Record system.

Any activity on the My Health Record system is recorded, and a log of activities can be viewed by the System Operator and the patient. If a pharmacist inadvertently accesses a patient's record, this should be noted in the patient history in the pharmacy's dispensing software to enable follow-up, if required.[6]

For more information on managing access to the My Health Record system, see the latest version of the PSA *My Health Record Guidelines for Pharmacists*.[6]

Selecting or preparing the medicine

Barcode scanners

Barcode scanners may be used to reduce data entry and improve efficiency when electronic prescriptions are presented to an electronic transfer of prescriptions (ETP)-enabled pharmacy.

Barcode scanners are also recommended for minimising the potential for dispensing errors. Pharmacists should use barcode scanners to verify selection of the correct product and minimise the risk of incorrect:

- product selection from a drop-down list
- product selection from a shelf
- labelling of a product.

Scanning to verify correct selection should occur immediately before attaching the label.

Pharmacists must recognise, however, that barcode scanners are not a substitute for manual checking processes, such as cross-checking with the accompanying original prescription.

Compounding

Compounding involves the preparation and supply of a single unit of a therapeutic product intended for a specific patient. Preparation of therapeutic products for general or wholesale supply (i.e. not for direct supply to a specific patient) is considered manufacturing, and requires a manufacturing licence.[5]

Compounding undertaken during the dispensing process varies in complexity, from the reformulation of commercial products and simple compounding to complex compounding requiring special competencies, equipment, processes or facilities.[17]

Pharmacists should refer to the Pharmacy Board of Australia *Guidelines on Compounding of Medicines*[36] and the PSA *Australian Pharmaceutical Formulary and Handbook*[17] for detailed guidance on professional obligations when compounding.

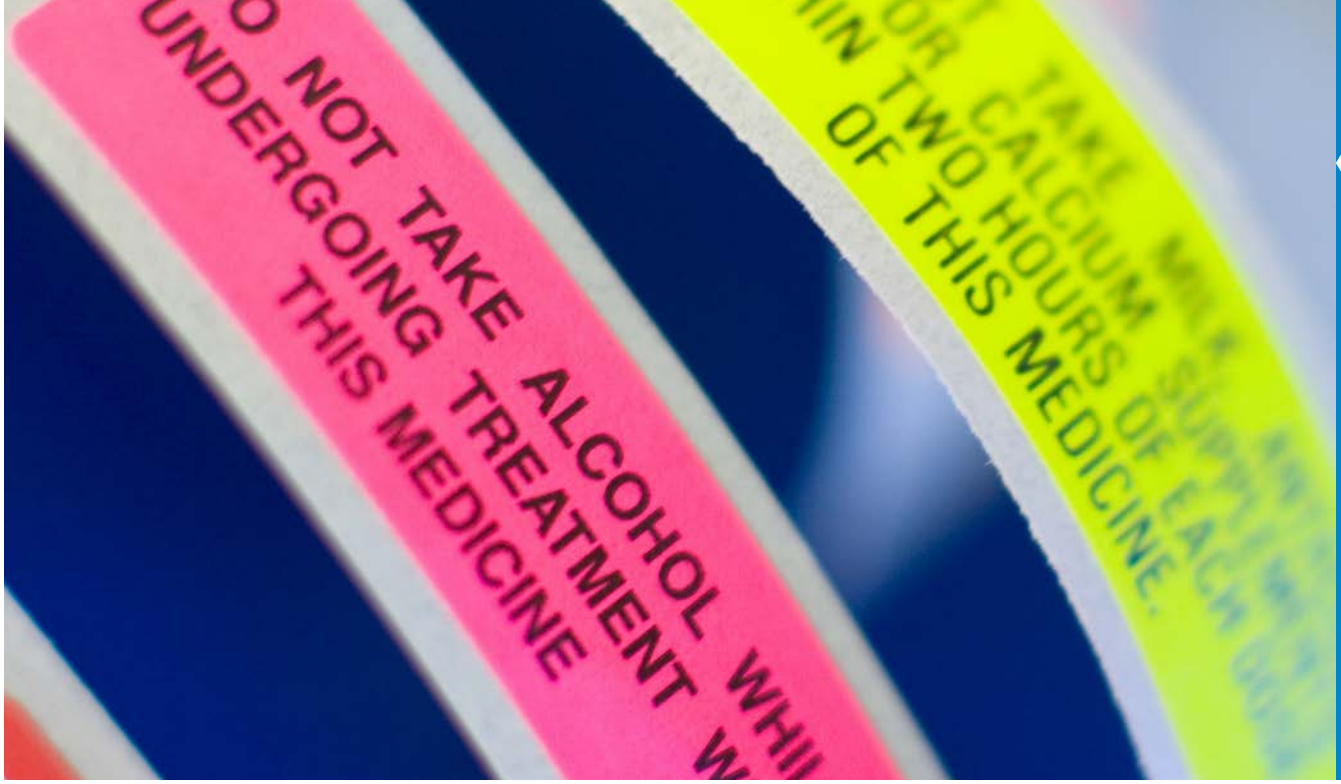
Repackaging medicines

Packaging preserves the stability and quality of medicine products, as well as protecting them against tampering.

When medicines are repackaged (e.g. in dose administration aids, for Staged Supply), the packaging and packing process needs to conform to prescribed standards to:

- ensure the suitability of the medicine
- protect against moisture, light and oxygen
- protect against biological contamination
- protect against physical damage
- prevent interaction between the medicine and packaging (e.g. through leaching or absorption)
- be resistant to opening by children, if the medicine presents a significant risk of toxicity if accidentally ingested
- carry the correct information and identification of the medicine.[37,38]

Pharmacists should refer to the Pharmacy Board of Australia *Guidelines on Dose Administration Aids and Staged Supply of Dispensed Medicines*,[28] the PSA *Guidelines for Pharmacists Providing Dose Administration Aid (DAA) Services*[39] and the PSA *Professional Practice Standard 15: Dose Administration Aid Service*.[3]



Labelling

State or territory legislation outlines the labelling requirements for dispensed medicines. Minimum requirements are summarised by the Pharmacy Board of Australia (see Box 2).

Box 2. Label content for dispensed medicines

- Brand and generic names of the medicine, and strength, dose form and quantity supplied
- Specific directions for use, including frequency and dose
- Patient's name or, in the case of an animal, the owner's name and the kind of animal
- Date of dispensing or supply
- Initials of the dispensing pharmacist (and, if different, initials of the pharmacist checking and issuing the medicine)
- A unique identifying code for the dispensed medicine
- Name, address and telephone number of the pharmacy or pharmacy department at which the medicine was dispensed
- Applicable storage directions and expiry date of the medicine
- The words "Keep out of reach of children"

Reference: Pharmacy Board of Australia[4]

Labelling compounded medicines

In addition to the labelling requirements for dispensed medicines (see Box 2), the label of a compounded medicine must include[4,17]:

- the name and concentration of each active ingredient (especially if a formulation other than a standard pharmacopoeial formulation is used)
- the name and concentration of any added preservatives
- the name of the formula as described in a standard pharmacopoeial reference book (where applicable).
- the words "This product has been compounded by the pharmacist".

Placement and legibility of labels

Dispensing labels should be firmly attached to the primary container, where possible. The placement of the label should not obscure important manufacturer information (e.g. expiry date, storage conditions, name and strength of the medicine).[17]

Where placement of the label on the primary container would compromise the patient's ability to use the medicine (e.g. as a result of the size or construction of the container), the label may be placed on the outer packaging. Alternatively, purpose-designed tags or 'winged' labels may be used.[17]

The label should be printed in clear and legible English, and be durable for the expected duration of use of the medicine. The pharmacist should label medicines with consideration of patient needs—for example, poor eyesight, health literacy, and cultural and linguistic diversity.[17] Accurate translations of other languages may be included in addition to English instructions, if appropriate.[4]

Cautionary advisory labels

Cautionary advisory labels (CALs) are a convenient and effective way for pharmacists to reinforce verbal communication with patients about the safe and effective use and storage of medicines. The *Australian Pharmaceutical Formulary and Handbook*[17] outlines CAL recommendations for specific medicines.

CALs should always be used unless there is a good reason not to. Pharmacists are expected to use their knowledge and professional judgement when deciding whether to omit one or more CALs for a particular patient or circumstance, except where legislation requires that certain labels must be used.[17]

The choice of which CALs to use for a specific patient or circumstance is a unique responsibility of pharmacists (not dispensary support staff). It is the responsibility of the pharmacist in charge to ensure that the dispensing workflow enables both the pharmacist and the dispensary support staff to efficiently carry out the tasks appropriate to their roles.

The Standard for the Uniform Scheduling of Medicines and Poisons contains lists of medicines that must be labelled with specifically worded warnings. State or territory legislation may have additional requirements for CALs.[4]

CALs are intended to reinforce, rather than replace, verbal counselling. Pharmacists should confirm that patients understand the meaning of the CALs that have been applied to their medicines. This is particularly important for patients with limited health literacy or who are culturally and linguistically diverse.

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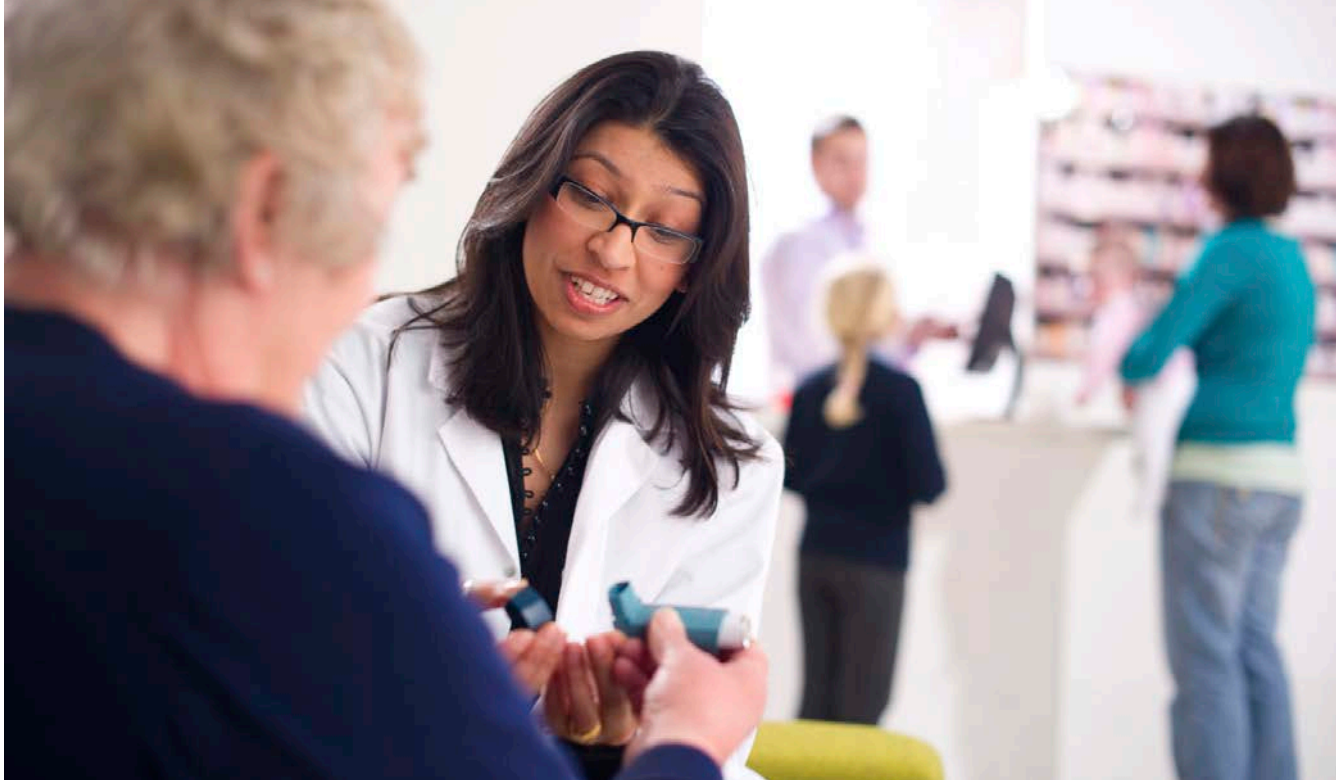

Supplying and counselling

Final checking

The pharmacist is responsible for ensuring that the entire dispensing process has been carried out according to good pharmacy practice.

At the point of supplying the medicine and counselling the patient, the pharmacist should place their initials or signature in the prescription records of the pharmacy, and any other place according to relevant legislation, accepting responsibility for the accuracy and completeness of dispensing.[4]

Correctly identifying the patient

The pharmacist should ensure that patient identity is confirmed before supplying the medicine to the patient and counselling, both to prevent dispensing errors and to protect patient privacy. At least three patient identifiers should be used.[13]

Patient counselling

Patient counselling is an important part of the process of dispensing medicines. Counselling is a two-way communication process between the pharmacist and the patient,[3] and can occur at any point in the dispensing process.

It provides an opportunity to elicit the necessary information from a patient, identify and resolve MRPs, and provide the required information to enable safe and effective use of medicines. It is the final check to ensure that the correct medicine is supplied to the correct patient.[4]

When dispensing repeat prescriptions, counselling provides an opportunity to ascertain whether the patient is taking the medicine correctly, whether the medicine is having the desired outcome or whether there are unwanted effects.[4]

Face-to-face counselling is the best way of communicating information about medicines. When face-to-face counselling is not possible or practicable, pharmacists should ensure that they can still obtain and provide the required information to ensure the safe and effective use of medicines (see "Indirect dispensing").

Counselling for medicines should involve discussion of[3]:

- the indication and instructions for use
- expected outcomes
- potential adverse reactions, and actions to be taken if adverse reactions or interactions occur
- storage requirements.

Pharmacists should use appropriate techniques to ensure patient understanding of counselling provided and confirm that they can use the medicine correctly. Counselling should also include demonstration of the appropriate use of associated delivery aids, therapeutic devices or dose administration aids.[3]

In certain circumstances, more detailed information may be required (see Box 3).

Counselling should take place in an environment that recognises the patient's right to privacy.[3] The pharmacist should make every effort to counsel, or to offer to counsel, the patient whenever a medicine is supplied. However, the pharmacist must respect the right of the patient not to be counselled.[4]

Written information such as Consumer Medicines Information (CMI) leaflets, CALs and PSA Self Care Fact Cards should be provided to supplement verbal counselling (see Appendix 4).

Box 3. Circumstances requiring more detailed counselling

More detailed counselling may be required when:

- the patient is new to the pharmacy
- the medicine is new for the patient or there is a change in strength from a previous prescription
- there are special administration instructions for the medicine
- the prescription is for a child, an older person, or a person at risk of medication misadventure (e.g. polypharmacy)
- there are special patient needs (e.g. visual, auditory or cognitive impairment; cultural and linguistic diversity)
- directions for use are absent or inadequate (e.g. 'mdu' or 'to be used as directed')
- the medicine has a narrow therapeutic index or requires therapeutic monitoring (e.g. methotrexate, warfarin, digoxin, phenytoin)
- the medicine is a controlled drug
- a potential or actual MRP has been identified and a clinical intervention has, or needs to be, performed
- supply of the medicine is considered unsafe or inappropriate
- the prescriber is not in agreement about resolving a MRP.

Reference: Adapted from Pharmacy Board of Australia[4]

Delegation and supervision in the dispensing process

A pharmacist is responsible for[4,6]:

- assessing the appropriateness of medicines in relation to the medication history, and for declining supply if they believe that use will be unsafe or inappropriate
- selecting the product intended by the prescriber and appropriate for the patient
- confirming the required formulation for medicines that are to be compounded
- ensuring the quality of data in the pharmacy's dispensing system, including accurate dispensing records being entered against the correct patient
- checking the dispensed medicine against the prescription and patient record (including shared electronic records, where relevant)
- counselling the patient and performing the final check
- ensuring that access to patient records is compliant with pharmacy policy
- maintaining patient privacy and confidentiality throughout the dispensing process, including when counselling the patient and at the point of supply of the medicine.

Individual pharmacists may be responsible for certain aspects of the dispensing processes. Each pharmacist should be conscious of the risks associated with fragmentation of the dispensing process, and satisfied that responsibility, accountability and patient welfare are being preserved. A pharmacist must not delegate their professional responsibilities to a dispensary assistant/technician working under their supervision.

Supervision of dispensary assistants/ technicians

The duties of dispensary assistants/technicians should be defined in position descriptions and standard operating procedures.

A pharmacist has the professional responsibility for all activities undertaken by dispensary assistants/technicians. This includes ensuring that dispensary assistants/technicians:

- observe all requirements for patient confidentiality and privacy
- are personally supervised by a pharmacist
- are only assigned to undertake tasks commensurate with their education, training and experience
- refer any situation requiring professional judgement or discretion to the pharmacist
- work in accordance with a position description and duty statement contained in the pharmacy's dispensary practice protocol
- comply with all relevant policies, procedures and legal obligations.

The pharmacist is responsible for determining whether an individual is appropriately educated, skilled and experienced to perform the role of a dispensary assistant/technician. This will include consideration of sufficient relevant practice experience, and/or completion of relevant education and workplace training.[4]

A pharmacist should not supervise more than two dispensary assistants/technicians involved in dispensing processes at any one time. Higher numbers must be justifiable with respect to the pharmacist's workload and responsibilities.[4]

Risk management

A number of risks associated with the dispensing process must be managed to ensure a consistent and high level of care is provided to patients. Risk management should focus on minimising the potential for dispensing errors (see Box 4).[5]

Standardised dispensing process

Pharmacists should ensure that standard operating procedures for the dispensing process are followed to minimise the risk of dispensing errors, near misses and medicine safety incidents. The Pharmaceutical Defence Limited *Guide to Good Dispensing* lists routine checks and procedures to guide the dispensing process.[5]

Workloads

Pharmacists must consider and manage their workloads to ensure patient safety, reduce the risk of dispensing errors, and promote their own health and wellbeing.[4] If the dispensing workload for an individual pharmacist is 150–200 items per day, it is suggested that use of intern pharmacists or trained dispensary assistants/technicians to manage the workload should be considered.[4] However, the number of items dispensed is only one factor that should be considered in determining workload.

Staffing levels in the dispensary should be sufficient to provide patient-centred care, and satisfy work health and safety requirements. The number of pharmacists, dispensary assistants/technicians and other pharmacy support staff should reflect the range and nature of services provided, other workplace responsibilities and the capacity of the workforce.

The *Fair Work Act 2009*[40] outlines maximum weekly hours for employees. It also provides guidance on determining whether additional hours are reasonable (for the employee).

Box 4. Dispensary risk management procedure

The following actions may be considered in managing risk in the dispensary:

- establishing an efficient dispensary workflow to limit distractions and interruptions
- managing the workload of pharmacists and dispensary assistants/technicians
- adjusting the dispensary environment (e.g. allowing sufficient workbench space for prescription assembly, adequate lighting)
- monitoring the dispensing output and stocking automated dispensing systems
- providing regular dispensary training to all pharmacy staff
- using barcode scanners to input prescription details and to verify medicine selection
- using a container to keep all items together when dispensing multiple items for a patient
- establishing an audit trail of the pharmacist's responsibilities and actions (e.g. initialling dispensing label)
- documenting and evaluating identified issues and appropriate response.

References: Sansom[17]; PDL[5]

Incident management

Under the Australian Charter of Healthcare Rights,[41] patients have the right to comment on, and complain about, health care they have received.

Standard operating procedures

The pharmacy should have standard operating procedures to manage complaints. The pharmacist should:

- make patients aware of the process for raising issues or complaints
- handle all complaints
- ensure the privacy of the complainant
- show concern and willingness to correct any error
- express regret for what has happened, when appropriate
- advise the prescriber if any incorrectly supplied medication was used
- notify their professional indemnity insurer
- record all relevant information relating to the incident at the time.

Systematic and complete documentation and record keeping in the dispensing process are critical in supporting a pharmacist's response to a complaint.

Indemnity insurance

All registered practising pharmacists with general, limited or provisional registration must have professional indemnity insurance under section 129 of the *Health Practitioner Regulation National Law*, as in force in each state and territory. Practitioners can be covered by their own or third-party professional indemnity insurance arrangements. The Pharmacy Board of Australia's Registration Standard: Professional Indemnity Insurance Arrangements does not apply to students or pharmacists with non-practising registration.[42]

In the event of an incident

In the event of an error or other clinical incident, pharmacists should act in accordance with the Australian Open Disclosure Framework.[43] The pharmacist should engage in an open discussion with the patient about any adverse event that has resulted in harm to the patient while receiving health care. The discussion is designed to be an exchange of information between the parties.

Pharmacists are encouraged to contact their indemnity insurance agency for incident support and advice.

Clinical incidents related to the My Health Record system

Any incidents of clinical significance involving the My Health Record system must be reported by the pharmacist to the My Health Record helpline (1800 723 471, available 24 hours, 7 days) as soon as possible. These incidents may relate to the system directly or the behaviour of clinical software when interacting with the My Health Record system. They may be related to safety, usability, technical, privacy or security issues.[44]

For more information on managing clinical incidents in the My Health Record system, see the latest version of the PSA *My Health Record Guidelines for Pharmacists*.[6]

In the event of a data breach

A data breach occurs when personal information held by an organisation is lost, or subjected to unauthorised access or disclosure.[45] Examples of a data breach in pharmacy include hacking of the dispensing computer containing personal information, and personal information being mistakenly provided to the wrong person.

If a data breach occurs that is likely to result in serious harm to any of the individuals to whom the information relates, pharmacists are required to notify the affected individuals and the Office of the Australian Information Commissioner (OAIC). Notification should be made through the Notifiable Data Breach form at: https://www.oaic.gov.au/NDBform

For guidance on managing data breaches in accordance with the *Privacy Act 1988* (Cth), pharmacists should refer to the OAIC guide.[46]

Data breaches related to the My Health Record system

In the event of unauthorised access to a patient's My Health Record through the pharmacy, by someone other than an employee of the pharmacy, the complaint is to be referred to the Responsible Officer of the healthcare organisation. Any suspected security breach should be reported to the police and, if relevant, the System Operator and/or the OAIC.[6]

For more information on managing data breaches related to the My Health Record System, see the latest version of the PSA *My Health Record Guidelines for Pharmacists*.[6]

Appendix 1: Brand substitution of PBS medicines

Scope

This appendix provides guidance to pharmacists on brand substitution of generic or biosimilar medicines when dispensing a pharmaceutical benefit item (on a Pharmaceutical Benefits Scheme [PBS] or Repatriation Pharmaceutical Benefits Scheme [RPBS] prescription). The appendix must be considered with the parent document, *Dispensing Practice Guidelines*.

Terminology

Bioequivalent (generic) medicine: an identical version of an already registered medicine that produces similar plasma concentrations of the same active ingredient.

Biosimilar medicine: a highly similar version of an already registered biological medicine (the reference biological medicine) that has been assessed to be highly similar to the reference biological medicine in terms of safety, effectiveness, physicochemical characteristics, biological characteristics and immunological characteristics.[47]

Substitutability

Under the PBS, 'a'-flags are used to indicate that different pharmaceutical benefit items are equivalent for the purposes of substitution by the pharmacist at the time of dispensing, without reference to the prescriber.

The Pharmaceutical Benefits Advisory Committee has determined that products that are 'a'-flagged may be interchanged without any expected difference in clinical effect.[48]

If brands are not 'a'-flagged, it is unknown whether they are bioequivalent or biosimilar. There may be several reasons for this—for example, bioequivalence data may not have been considered necessary when the products were approved for marketing, or advice or data have not been forthcoming from sponsors. This does not necessarily indicate a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.[48]

Important considerations when the pharmacist is considering or undertaking brand substitution are outlined below. These should be taken into account for substitution between the innovator and a generic product, as well as substitution between different generic products.

Substitution considerations

Substitution not permitted

If the prescriber indicates on the prescription that brand substitution is not permitted, the pharmacist must only dispense the prescribed brand. The patient must not be offered a choice of alternative brands.

If the prescriber has ordered a specific brand and marked on the prescription that substitution is not permitted, and the patient requests substitution with a different brand, the pharmacist should either discuss the matter with the prescriber or refer the patient back to the prescriber for further discussion.

If substitution has been disallowed (by the prescriber) but the pharmacist is unable to source the particular brand prescribed (e.g. it is out of stock at the suppliers), the pharmacist must discuss the matter with the prescriber. The pharmacist should present clear information (e.g. when stock may be able to be sourced) or options (e.g. other available brands) to the prescriber.

Informed patient consent

The patient's health must always be the pharmacist's prime consideration in any brand substitution decision. The pharmacist must respect the right of the patient to choose a brand of medicine.[2] Any decisions to substitute one brand for another should not place patients at risk.

Having confirmed that the prescriber has not disallowed substitution, the pharmacist must obtain patient consent before substitution. The pharmacist must consider safety and suitability of alternative brands for the patient, and provide adequate and appropriate information to the patient regarding the proposed substitution so that an informed decision can be made. Substitution may only occur after consultation with, and agreement of, the patient.

If the patient is offered a different brand or enquires about alternative brands, information that may assist the patient in making an informed decision about brand choice includes cost of the medicine, physical characteristics and formulation of the medicine, type of administration device, allergies to excipients, and other medicines the patient is taking.

Pharmacists should have systems to ensure that all patients have the opportunity to request a generic or biosimilar medicine before dispensing occurs, and to record patient preferences regarding brand substitution in the patient's healthcare record in the dispensing software.

Multiple or repeated substitutions

Before substituting a medicine, the pharmacist should consider the impact of multiple brand changes on the patient—in particular, the potential for confusion and duplication of therapy.

Pharmacists must be vigilant when substituting brands to ensure that patients fully understand the substitution. In particular, they should always aim to provide patients with the same brand for long-term therapies.

In some circumstances, substitution may be unavoidable— for example, due to an inability to source a particular brand that is out of stock at the suppliers. If substitution is not disallowed by the prescriber, the pharmacist must provide thorough advice to the patient (e.g. about differences in product presentation) whenever substitution occurs under such circumstances.

Situations requiring caution

For some medicines or in some circumstances, it may be advisable to avoid brand substitution even if bioequivalent or biosimilar brands are available.

Medicines with a narrow therapeutic index (critical dose medicines).[49] Although any causal relationship between brand substitution of bioequivalent medicines and adverse outcomes is unproven, special consideration is warranted with medicines that have a narrow therapeutic index because significant adverse effects or loss of efficacy may result. Patients with well-controlled epilepsy should not have their anti-epileptic medicine substituted; if brand substitution is considered necessary, the prescriber's advice should be sought first.[50]

Risk of confusion, anxiety or harm. Patients at risk of confusion, anxiety or harm may include those on complex medicine regimens, who have cognitive or vision impairment, or with a non-English-speaking background.

Possible negative impact on adherence. For some patients (e.g. people with a mental illness), a lack of consistency in the medicine brand may reduce adherence.

Excipients. Some patients are allergic to certain excipients (e.g. colouring agent) or have an intolerance to them (e.g. lactose, gluten). Patients may also have religious or cultural concerns about an inactive ingredient (e.g. gelatin).

Device. Where a device is used to administer the medicine, the device may differ between brands. This may affect adherence.

Counselling

During the brand substitution process, pharmacists should educate patients about their medicines generally and about informed brand choices. Pharmacists have an integral role in providing information to patients, including information about active ingredient names, cost of medicines, availability of generic medicines, and how to manage their medicines for a safe and effective outcome.

Pharmacists have a responsibility to inform patients about the chosen brand of medicine and to ensure that they know how to use it correctly.

Refer also to "Patient counselling".

Optimising patient health outcomes

Pharmacists should encourage (or offer to assist) patients to have their medication regularly reviewed to check for duplication of the same medicine as different brands. Some patients may also benefit from other quality use of medicines services, such as Home Medicines Review, MedsCheck or Diabetes MedsCheck.

Pharmacists are encouraged to discuss brand substitution issues with local prescribers to maintain and improve professional relationships, and minimise any conflict or misunderstanding. Pharmacists have a role in providing medicine-related information to other health professionals and should work collaboratively to enhance health outcomes for the patient.[3]

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Appendix 2: Other supply arrangements

Pharmacists must comply with rules and regulations that apply to the particular medicine supply arrangement being implemented. The most common scenario is dispensing of items subsidised through the Pharmaceutical Benefits Scheme (PBS) or the Repatriation Pharmaceutical Benefits Scheme (RPBS). However, PBS/RPBS dispensing can involve extended or alternative supply arrangements, and there are also other (non-PBS/RPBS) supply arrangements. Some examples are provided below.

ALTERNATIVE AND EXTENDED PBS SUBSIDISATION ARRANGEMENTS	
Section 100 items	Under section 100 of the *National Health Act 1953*, a number of medicines are available as PBS items but under alternative arrangements: • Highly Specialised Drugs Program (e.g. HIV antiretroviral therapies, medicines used in the treatment of hepatitis B, clozapine)—see: www.pbs.gov.au/browse/section100 • Efficient Funding of Chemotherapy—see: www.pbs.gov.au/info/browse/section-100/chemotherapy • Botulinum Toxin Program—see: www.pbs.gov.au/info/general/changes-to-certain-s100-programs • Growth Hormone Program—see: www.pbs.gov.au/browse/section100-gh and www.pbs.gov.au/general/changes-to-certain-s100-programs/faqs-growth-hormone-1-dec-2018.pdf • In Vitro Fertilisation Medicines Program—see: www.pbs.gov.au/general/changes-to-certain-s100-programs/revised-faqs-ivf-medicines-25-june-2015.pdf • Opiate Dependence Treatment Program—see: www.pbs.gov.au/browse/section100-md
Closing the Gap for PBS prescriptions	The Closing the Gap (CTG) PBS Co-payment Measure helps an Aboriginal or Torres Strait Islander person with, or at risk of, chronic disease to obtain most prescription medicines at a lower price, or free of charge (with a Health Care Card). The prescriber assesses eligibility for the scheme and arranges registration. Prescriptions written under this measure are referred to as CTG prescriptions, and the normal PBS prescription requirements apply. Pharmacists need to: • indicate in the dispensing software that a CTG prescription is being dispensed • check that prescriptions are correctly annotated by the prescriber • ensure that the CTG annotation code is keyed for each prescription being dispensed. More information is available at: https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/closing-gap-pbs-co-payment-measure
ARRANGEMENTS FOR ACCESSING UNAPPROVED MEDICINES	
Special Access Scheme	This arrangement provides patient with access to medicines that are not in the Australian Register of Therapeutic Goods; see: www.tga.gov.au/form/special-access-scheme
Personal Importation Scheme	This arrangement allows individuals to import unapproved therapeutic goods for personal use; see: www.tga.gov.au/publication/personal-import-scheme and www.tga.gov.au/sites/default/files/access-personal-import-guidelines.pdf
Clinical trials	This arrangement allows 'unapproved' therapeutic goods to be lawfully supplied for use solely for experimental purposes in humans; see www.tga.gov.au/clinical-trials
OTHER MEDICINES WITH UNIQUE SUPPLY ARRANGEMENTS	
Medicinal cannabis	A regulatory framework to allow Australian patients to legally access medicinal cannabis products has been developed. Further advice is available from www.tga.gov.au/medicinal-cannabis-guidance-documents, and state or territory health departments. Also see: https://my.psa.org.au/s/article/Medicinal-Cannabis-Education-Resources (PSA member-only access)

Appendix 3: Sensitive information

Sensitive information is personal information that, if disclosed or handled inappropriately, can leave an individual vulnerable to discrimination, mistreatment, humiliation or embarrassment. It may encompass any information that defines or infers race or ethnic origin; political opinions; religious beliefs and affiliations; philosophical beliefs; sexual preferences and orientation; criminal record; or health, genetic or biometric information.[15]

Legislation in some states and territories prevents the disclosure of certain sensitive information unless express or written consent is provided.[32] Uploading such information to a patient's My Health Record would be considered disclosure. State- and territory-specific information is provided in the following table.

State and territory legislation relevant to uploading sensitive information to My Health Record[6]

STATE OR TERRITORY	ACT	SECTION
Australian Capital Territory	Public Health Act 1997	Sections 110 and 111 www.legislation.act.gov.au/a/1997-69/current/pdf/1997-69.pdf
New South Wales	Public Health Act 2010	Section 56 www.legislation.nsw.gov.au/#/view/act/2010/127/part4/div3/sec56
Northern Territory	No specific requirements apply	
Queensland	Public Health Act 2005	Section 55 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.55 Sections 77 to 79 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.77 Sections 105 to 107 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.105 Sections 175 to 177 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.175 Sections 220 to 222 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.220 Sections 238 to 240 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.238 Sections 266 to 268 www.legislation.qld.gov.au/view/html/inforce/2018-01-01/act-2005-048#sec.266
South Australia	No specific requirements apply	
Tasmania	No specific requirements apply	
Victoria	No specific requirements apply	
Western Australia	No specific requirements apply	

Appendix 4: Counselling with Consumer Medicines Information leaflets

Scope

This appendix provides guidance to pharmacists on counselling with Consumer Medicines Information (CMI) leaflets in the dispensing process. The appendix must be considered with the parent document, Dispensing Practice Guidelines.

Terminology

The term CMI applies only to information that is prepared by the sponsor of a medicine in accordance with regulatory requirements. Sponsors of medicines have an obligation to provide written information about their products for patients, under the Therapeutic Goods Regulations 1990.[51]

Information contained in CMI leaflets is brand specific and must be consistent with the approved Product Information (PI). CMI leaflets must be written in a manner that will be easily understood by patients. They are made available as package inserts, as pads of leaflets and online,[52] as well as integrated with dispensing software.

Supporting patients through the provision of CMI

CMI leaflets can be used to provide medicines information to patients during the dispensing process and to engage patients in conversations about their medicines.

Patients in all pharmacy settings have a right to obtain information about their medicines.[41,53] Patients appreciate receiving written or verbal information about medicines they are taking, and there are benefits in providing information, particularly written information.[54-56] Use of CMI leaflets in a variety of pharmacy settings (e.g. community,[57] hospital,[58] transitions of care[59]) is influenced by many factors, including the patient's cultural and linguistic preferences, and the environment.

Barriers around CMI leaflets are often mentioned—for example, that they are out of date, too long, may not cater for certain population groups (e.g. children or people with a disability) and not always available electronically.

Despite these barriers, pharmacists are encouraged to use CMI leaflets as a tool to enhance the pharmacist–patient partnership and support informed decision making. This can occur through engaging in dialogue during counselling and promoting opportunities for follow-up. Patients can also read or refer to CMI leaflets in their own time, rather than relying on unverified information sources.

It has been reported that patient factors such as disease state, coping style, health literacy and occupation influence a patient's interest in reading and seeking written medicines information. Pharmacists therefore have a role in tailoring the counselling they provide to meet the patient's needs.[55,56]

The level of detail and nature of the information in CMI leaflets can be confusing for patients. Information is available to help patients familiarise themselves with the consistent format and type of information contained in CMI leaflets.[59,60]

Information about side effects is reported to be of key importance to patients.[61] It is important for pharmacists to discuss side effects in the right context and provide support, rather than avoiding the topic. Evidence about the relationship between patients reading about adverse effects in written medicine information and subsequently ceasing or changing medication is contradictory.[62] CMI leaflets can be used to guide the conversation with patients about adverse events and disease states, especially those that may cause alarm. Pharmacists are encouraged to read through the CMI leaflets with the patient, based on individual patient circumstances.[4]

Professional responsibilities

The Therapeutic Goods Administration requires that CMI leaflets (for medicines that have them) are made available to patients either inside the medicine pack or in a manner that will inform the patient about the medicine they have had administered or dispensed.[52] Pharmacists also have a professional obligation to provide all necessary and up-to-date information to enable patients to make informed decisions about their medicines.[3,4]

CMI leaflets should be regarded as a valuable tool for assisting the counselling process, not as an alternative to counselling. CMI leaflets should not be used to replace face-to-face counselling by pharmacists, which is considered the best way of communicating information about medicines.[4]

Pharmacists must not delegate medication counselling tasks to non-pharmacists.

CMI leaflets can increase patient knowledge, facilitate the appropriate use of medicines and thereby enhance therapeutic outcomes. They can also reduce the potential for adverse drug reactions through inappropriate use, and help patients to monitor any adverse effects and report them to a health professional in a timely manner.During a discussion with a patient, a pharmacist may:

- highlight sections of the CMI leaflet that are particularly relevant to the patient
- use the CMI leaflet to facilitate patient engagement, encourage the patient to read and seek clarification as necessary, and ensure that the patient understands the information
- provide supplementary information (e.g. PSA Self Care Fact Cards) to assist the patient's understanding of their condition or medication management issues.

Pharmacists must use their professional judgement and discretion in each situation to ensure that they are providing balanced information to the patient.[41]

Pharmacists may annotate the CMI leaflet with additional information appropriate for the patient. Any annotations made should be clearly identified and signed by the pharmacist who makes the additions. CMI leaflets must not otherwise be altered or abbreviated in any way by the pharmacist, because they are official product documents. Alterations and abbreviations of a CMI leaflet could expose pharmacists to legal action under product liability laws.

Providing CMI leaflets

Patients should have the opportunity to access the current version of the CMI leaflet each time a product is dispensed.

CMI leaflets have a role in helping pharmacists facilitate quality use of medicines, including[4]:

- if the patient is commencing a new medicine
- if brand substitution has occurred
- if the dosage form has been changed
- after each supply of medicine—regular reinforcement of information may be required (e.g. if the medication is cytotoxic or teratogenic, or has major contraindications for its use)
- at the request of the patient
- when the patient has special needs
- at regular intervals for medicines used for long-term therapy (e.g. every 6 months, or on dispensing the last repeat of a prescription with five repeats)
- when the pharmacist has received advice that a sponsor has made significant changes to the CMI.

CMI leaflets are brand specific. Therefore, pharmacists must be vigilant about any information that may need to be highlighted to the patient when brand substitution occurs, even when the patient is already familiar with, and well informed about, their medicine.

Pharmacists may need to specifically tailor the information contained in the CMI leaflet. They should consider this when dispensing high-risk medicines or in other situations where the provision of a CMI leaflet may be important—for example[4]:

- medicines that have a narrow therapeutic index or sedative properties, or are controlled drugs
- medicines with unusual dose forms or dosage regimens
- when the patient is a child or is taking many medicines
- when there is an acute illness or event.

Off-label use of medicines

A medicine listed in the Australian Register of Therapeutic Goods is described as being prescribed 'off-label' when its intended use is not included, or is disclaimed, in the approved PI or CMI leaflet, including use:

- for a different indication
- in a different age range
- with a different dose or route of administration.

Off-label use is permitted under certain clinically appropriate circumstances. It may occur more frequently when specialist prescribers are involved in the health care of the patient—for example, in palliative care, paediatrics and psychiatry. Off-label use may be appropriate if supported by high-quality evidence, or consensus opinion based on extensive experience.[63,64] Exceptional use may be justified by individual clinical circumstances.[63]

The prescriber may not always communicate off-label prescribing. A pharmacist's professional judgement may be required based on information on the dosage regimen, patient history or presentation of a non-Pharmaceutical Benefits Scheme (PBS) prescription. Clarification with the patient and/or prescriber may be required.

When a medicine has been prescribed for off-label use, additional care is required when counselling with a CMI leaflet to[65]:

- confirm the use of the medicine (as the patient may have concerns or confusion about why their condition is not listed in the CMI leaflet)
- counsel in the usual manner, with emphasis on the particular patient's needs or concerns
- highlight or annotate any important individualised differences
- explain how to monitor for potential side effects and what to do in the event of adverse effects
- provide information about the cost of the medicine
- make a professional judgement to either provide additional resources or information from other sources (where appropriate and available), or refer the patient back to the prescriber for additional information.

Documentation

Appropriate and accurate records assist medication management. Adequate documentation is an important component of risk management and quality patient care.

Pharmacists are encouraged to use reliable systems for documenting critical actions taken in relation to patient counselling. Pharmacists should also record details of the circumstance and reasons when, after exercising professional judgement, they withhold a CMI leaflet from the patient.

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