The revised *Dispensing Practice Guidelines* are currently undergoing consultation and review and as such have not been endorsed by the Pharmaceutical Society of Australia.
Dispensing Practice Guidelines
— 2nd DRAFT FOR REVIEW AND CONSULTATION

PSA Committed to better health
The PSA gratefully acknowledges the Australian Government for providing funding for these Guidelines.
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About the guidelines

The review of the Pharmaceutical Society of Australia's (PSA's) Dispensing Practice Guidelines was prompted by the introduction of the My Health Record system and the release of PSA's My Health Record Guidelines for Pharmacists.

This review follows one in 2017 that ensured consistency in the advice and guidance provided to pharmacists on dispensing medicines following release of the Pharmacy Board of Australia's Guidelines for Dispensing of Medicines (2015) and PSA's Professional Practice Standards (2017).

The 2017 review also consolidated and superseded three separate guidelines: Dispensing Practice Guidelines (1999), Guidelines for Pharmacists on PBS Brand Substitution (2004) and Consumer Medicine Information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). This amalgamation recognised that brand substitution and using Consumer Medicine Information (CMI) leaflets during counselling are core components of dispensing medicines.

Purpose and scope

The Dispensing Practice Guidelines (the 'Guidelines') assist pharmacists, intern pharmacists and pharmacy students to understand their professional obligations when dispensing medicines, and performing other associated tasks including brand substitution and the provision of CMI.

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 be best fulfilled.

The Guidelines can be used as a tool to support balanced and professional decision making and ensure 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.

The Guidelines are designed to be applicable to all practice settings in which pharmacists dispense medicines, including non-prescription dispense medicines. Some specialised dispensing activities (e.g. continued dispensing, staged supply, opioid substitution therapy) may be covered by other guidelines.

Guidelines produced by 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 should be used in conjunction with the Pharmacy Board of Australia's *Code of Conduct for Pharmacists*, 1 PSA's *Code of Ethics for Pharmacists*, 2 PSA's *Professional Practice Standards*, 3 particularly Standard 3: Dispensing and Other Supply Arrangements, the Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines* and PSA's *My Health Record Guidelines for Pharmacists*. 4 Pharmacists should also refer to other relevant reference texts including the *Australian Pharmaceutical Formulary and Handbook* (APF). 5

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.

**Terminology**

Please see the table below for definitions of terms commonly appearing in the guidelines.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Equivalent or related term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorised representative</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Clinical incident</td>
<td>A clinical incident is 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 and/or security issues. For specific guidance on clinical incidents associated with the My Health Record system, refer to the latest version of PSA's <em>My Health Record Guidelines for Pharmacists</em>. 39</td>
<td></td>
</tr>
<tr>
<td>Controlled Drug</td>
<td></td>
<td>Schedule 8 medicine, schedule 8 poison</td>
</tr>
<tr>
<td>Dispensary technicians</td>
<td>Individuals assisting in the dispensing process but who are not pharmacists, intern pharmacists or pharmacy students</td>
<td></td>
</tr>
<tr>
<td>Dispensing</td>
<td>The review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the medicine, including counselling, to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient</td>
<td></td>
</tr>
<tr>
<td>Health literacy</td>
<td>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</td>
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<tr>
<td>Healthcare Provider Identifier</td>
<td>A unique 16-digit number used to identify individual healthcare providers who deliver healthcare in the Australian setting</td>
<td>HPI-I</td>
</tr>
<tr>
<td>- Individual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare Provider Identifier</td>
<td>A unique 16-digit number used to identify organisations that deliver healthcare in the Australian setting</td>
<td>HPI-O</td>
</tr>
<tr>
<td>- Organisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual healthcare identifier</td>
<td>A unique 16-digit number used to identify individuals who receive or may receive healthcare in the Australian health system</td>
<td>IHI</td>
</tr>
<tr>
<td>My Health Record</td>
<td>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</td>
<td>Digital health record, eHealth record, Personally Controlled Electronic Health Record (PCEHR)</td>
</tr>
<tr>
<td>My Health Record system</td>
<td>The infrastructure and operational support for delivering My Health Records</td>
<td></td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
<td>Examples</td>
</tr>
<tr>
<td>-------------------------------------------</td>
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</tr>
<tr>
<td>Patient</td>
<td>A person who uses, or is a potential user of, health services, including their family, carers or agent</td>
<td>Consumer, healthcare recipient, client</td>
</tr>
<tr>
<td>Patient healthcare record</td>
<td>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</td>
<td>Dispensing record, medication profile, medication record, patient profile, patient record</td>
</tr>
<tr>
<td>Patient identifiers</td>
<td>For the purposes of these guidelines, 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.</td>
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</tr>
<tr>
<td>Pharmacist</td>
<td>A provisionally or generally registered practicing pharmacist registered with the Pharmacy Board of Australia within the Australian Health Practitioner Regulation Agency (AHPRA)</td>
<td>Intern pharmacist, registered pharmacist</td>
</tr>
<tr>
<td>Prescriber</td>
<td>A healthcare provider who is responsible for patient care, specifically medicines</td>
<td>Doctor, dentist, general practitioner (GP), nurse practitioner, optometrist, other approved non-medical prescribers, specialists</td>
</tr>
<tr>
<td>Sensitive information</td>
<td>A type of personal information that, if disclosed or handled inappropriately, can leave the individual vulnerable to discrimination, mistreatment, humiliation or embarrassment. It may encompass any information that defines or infers, e.g., race or ethnic origin, political opinions, religious beliefs and affiliations, philosophical beliefs, sexual preferences and orientation, criminal record, health, genetic or biometric information.</td>
<td></td>
</tr>
<tr>
<td>System Operator</td>
<td>The Australian Digital Health Agency is the My Health Record System Operator, as prescribed under the My Health Records Regulation 2012</td>
<td>SO</td>
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</tbody>
</table>
Introduction

Dispensing is a core clinical activity that enables pharmacists to ensure the safety and effectiveness of medicines. Dispensing must be patient-centred and support the quality use of medicines (QUM). QUM involves:

• 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 pharmacist’s role “ensures that all dispensed and supplied therapeutic goods and associated pharmacy services reflect the prescriber’s intentions, and are consistent with the quality use of medicines and the patient’s health goals and values.” This requires accessing appropriate clinical information, including the patient’s My Health Record.

Dispensing is a key component in the medicines management pathway, including review of medicine order, issue of medicine and provision of medicine information.

Good dispensing practices are essential to facilitate the safe provision of prescription medicines and devices.
The dispensing process

When dispensing medicines, pharmacists should ensure that:

- the prescription is valid, according to relevant legislation
- 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 duty of care to:

- apply their expertise
- use professional judgement to protect and promote the safety, health and wellbeing of patients
- maximise therapeutic outcomes in partnership with patients and prescribers.

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

- steps involved in the dispensing process (see Figure 1)
- 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 1. The dispensing process

Receiving a prescription

Ascertaining authority to prescribe

Obtaining supplementary information, ensure all patient identifiers are available
(see Reviewing prescribed medicines)

Determining the prescriber’s intentions, including the dosing instructions
(see Reviewing prescribed medicines)

Reviewing the medication history and obtain relevant patient information from other sources (e.g. My Health Record)
(see Reviewing prescribed medicines)

Processing the prescription
(see Recording and documentation)

Selecting or preparing the medicine

Labelling the medicine
(see Labelling)

Using a barcode scanner where packaging includes a barcode
(see Risk management)

Checking and re-checking all dispensing for accuracy and completeness
(see Risk management)

Counselling the patient, carer or agent
(see Counselling)

Accepting responsibility for dispensing process
(see Pharmacist responsibilities)

Following up with patient or prescriber as required
(See Communication)

Reference: Adapted from Pharmacy Board of Australia⁴
Reviewing prescribed medicines

The pharmacist has a professional responsibility to review medicines prescribed for patients in order to provide optimal health care. This review should be undertaken in collaboration with the patient.

The review of prescribed medicines should consider:

- 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 prescribed regimen (i.e. over- or under-use of medicines).

Correctly identifying the patient

The pharmacist should ensure patient identity is confirmed by collecting and recording patient identifiers. These include the patient’s:

- Medicare card number or DVA number
- surname
- given name
- date of birth
- gender
- address

These patient identifiers are required for validating a patient’s IHI and link the patient’s record in the pharmacy dispensing software with their My Health Record. Identifiers such as date of birth and gender are not currently routinely collected and recorded, and if missing, the patient’s identity cannot be validated. Patient identifiers may be considered sensitive information by the patient. While respecting individual choice, the pharmacist may wish to consider making the patient aware of the risks associated with the identifiers not being disclosed, and ensure any action is consistent with patient safety.

Obtaining additional information

The pharmacist has a professional obligation to ensure they have sufficient patient information to review the medicines prescribed.

Communication and collaboration with the patient and prescriber will be the primary sources of additional information. The pharmacist should use professional judgement to determine if they have sufficient information, or if further clinical information is required, based on the episode of care being provided.

The My Health Record system provides the pharmacist with an accessible source of information that may assist them to meet professional obligations and provide safe and appropriate patient care. The pharmacist should only access a patient’s My Health Record and view documents in the record that they reasonably believe will assist them to provide better patient care, for example, to:

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

The My Health Record 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 for patient’s to control access to information in their My Health Record and discuss why they need access to information if access has been restricted.

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 PSA’s My Health Record Guidelines for Pharmacists.

Real-time prescription monitoring systems (to date, includes DORA in Tasmania, SafeScript in Victoria, 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. These currently operate independently of the My Health Record system, and will need to be accessed separately where appropriate.

The pharmacist should ensure reasonable attempts are made to access information required to inform appropriate clinical decisions. It is important that pharmacists recognise these systems are only one of a number of potential sources of patient health information, and should not be assumed to be a complete record. The pharmacist should consider the need to consult other appropriate sources of information (e.g. other health professionals) in addition to, or instead of, these systems, in order to provide safe and appropriate patient care.

Dispensing and supply arrangements

Pharmacists must comply with relevant Commonwealth, state or territory legislation associated with the dispensing and supply of medicines. The most common scenario involves the dispensing of items subsidised through the Pharmaceutical Benefits Scheme (PBS) or the Repatriation Pharmaceutical Benefits Scheme (RPBS). Other arrangements include extended or alternative PBS or RPBS supply arrangements and non-PBS supply arrangements. Pharmacists must carefully consider and confirm their obligations if they are not familiar with a specific supply arrangement.

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).

Controlled Drugs

The dispensing of Controlled Drugs (also known as Schedule 8 medicines and poisons) is governed by additional Commonwealth, state or territory rules or requirements. Pharmacists must refer to or be familiar with the relevant legislation for information about the legal requirements for dispensing these medicines.

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 (see ‘Communication with prescribers’).

Patient counselling for Controlled Drugs should include relevant advice about specific requirements for that medicine (e.g. repeat dispensing intervals) and any warnings about the potential for drowsiness or sedation (if applicable) (see ‘Counselling’).

Other arrangements

The establishment of other supply arrangements may be associated with the need to incorporate additional risk management measures while facilitating appropriate access to eligible patients. (see Appendix 2).
Recording and documentation

The patient healthcare record should be created or updated in the pharmacy dispensing software at 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 patient healthcare record may include:
- patient details (e.g. date of birth)
- medical history, including medical conditions, allergies and details of adverse reactions
- 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 prescriber, reasons for early or multiple repeats supplied, and follow-up actions required.

The patient record in the dispensing software is an important source of patient information, but should not be assumed to be a complete record nor necessarily reflect patients’ current medicine use.

The pharmacist should also document details of any medication-related problems (MRPs) identified during the dispensing process and clinical interventions performed. Examples of MRPs that may be identified include:
- Potential over-use or duplication of medicines, or over-treatment of conditions
- A medical condition (e.g. poorly controlled hypertension) which may require enhanced therapy or improved medication adherence
- A need for preventive therapy, such as the requirement for 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.
- Receiving a request from a patient for further information regarding the medicine or disease management.
- The reasons for refusing 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. Pharmacists should be cognisant of the potential for patients and other health professionals to view the records when documenting details in the dispensing software or patients’ My Health Record.

For more detailed information about performing and documenting MRPs and clinical interventions, see PSA’s Guidelines for pharmacists performing clinical interventions.

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 those exceptions allowed by the Privacy Act 1988®). The Australian Privacy Principles® give legislative force to Care Principle 2 of PSA’s Code of Ethics for Pharmacists® regarding confidentiality of information.
Patient information should only be used and disclosed with the patient’s consent, unless required by law. Patient consent is required prior to disclosing patient information to a carer or agent 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 responsible person, providing the pharmacist is satisfied the disclosure:

- is reasonable and necessary to provide appropriate care or treatment, or is made for compassionate reasons
- is not contrary to any wish about disclosing health information they do, or should, know about.

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

**Contributing to the My Health Record system**

The pharmacist can upload dispensing information directly to a patient’s My Health Record if:

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

To ensure dispensing information is 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.

**Sensitive information**

Currently, patients provide standing consent for pharmacists directly involved in their care to upload information to their record. The pharmacist does not need to obtain express or written consent, except where the prescribed State or Territory law requires it to upload sensitive information (e.g. information relating to screening and/or diagnoses or certain cancers or notifiable conditions such as HIV infection). See Table 1.

Pharmacists should exercise professional judgement prior to uploading sensitive information. For example, psychotropic medicines, antimicrobials for sexually transmissible infections or medicines for sexual dysfunction may be considered as ‘sensitive’ by an individual patient.

**Table 1. State and Territory legislation relevant to uploading of sensitive information**

<table>
<thead>
<tr>
<th>State or Territory</th>
<th>Act</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Capital Territory</td>
<td>Public Health Act 1997</td>
<td>Section 110 to 111</td>
</tr>
<tr>
<td>New South Wales</td>
<td>Public Health Act 2010</td>
<td>Section 56, 92</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>No specific requirements apply</td>
<td></td>
</tr>
<tr>
<td>Queensland</td>
<td>Public Health Act 2005</td>
<td>Section 55, 77 to 79, 105 to 107, 175 to 177, 220 to 222, 238 to 240, 266 to 268</td>
</tr>
<tr>
<td>South Australia</td>
<td>No specific requirements apply</td>
<td></td>
</tr>
<tr>
<td>Tasmania</td>
<td>No specific requirements apply</td>
<td></td>
</tr>
<tr>
<td>Victoria</td>
<td>No specific requirements apply</td>
<td></td>
</tr>
<tr>
<td>Western Australia</td>
<td>No specific requirements apply</td>
<td></td>
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</tbody>
</table>

Regardless of consent requirements, it is good practice for pharmacists to advise patients when information is being uploaded to the patient’s My Health Record (e.g. by using tools indicating the pharmacy’s use of the My Health Record system), as well as proactively discussing 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, refer to your software manual or contact your vendor for information on how to prevent dispense records from being uploaded to My Health Record (as the step required differs slightly for each software). 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.
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, 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 PSA’s My Health Record Guidelines for Pharmacists.

Recording Pharmacist Only medicines

The pharmacist should record the supply of Pharmacist Only medicines in accordance with relevant 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.
Labelling

State or territory legislation outlines the labelling requirements for dispensed medicines.

Box 2. Dispensing label content required by legislation

- Brand and generic names of the medicine, the strength, the dose form and the 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, the 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*

Labelling compounded medicines

In addition to the labelling requirements for dispensed medicines (see Box 2), the label of a compounded medicine must include15:

- 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 dates, storage conditions and the name and strength of the medicine).5

Where placement of the label on the primary container would compromise the patient’s ability to use the medicine (i.e. due to size or construction of the container), the label may be placed on the outer packaging or alternatively purpose designed tags or ‘winged’ labels may be used.5

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.5 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 APF 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.5

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 Poisons Standard 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.
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

It provides an opportunity to elicit the necessary information from a patient, identify and resolve medication-related problems, provide the required information to enable safe and effective use of medicines, and is the final checking process to ensure the correct medicine is supplied to the correct patient.4

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

Face-to-face counselling is the best way of communicating information about medicines, however where that is not possible or practicable, pharmacists should ensure 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 of3:

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

Pharmacists should use appropriate techniques to ensure patient understanding of counselling provided and confirm 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).

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, or cultural and linguistic diversity)
- there is a lack of, or inadequate, directions for use (e.g. ‘mdu’ or ‘to be used as directed’)
- the medicine has a narrow therapeutic index or requires therapeutic monitoring (including methotrexate, warfarin, digoxin, phenytoin)
- the medicine is a Controlled Drug
- a potential or actual medication-related problem 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 medication-related problem.

Reference: Adapted from Pharmacy Board of Australia4
Counselling should take place in an environment that recognises the patient’s right to privacy. 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.

Written information such as CMI leaflets, CALs and PSA Self Care Fact Cards should be provided to supplement verbal counselling (see Appendix 3).

Refusal to supply

Pharmacists should exercise professional autonomy, objectivity and independence. They have the right to refuse to supply medicines if they believe use is unsafe or inappropriate, even if the prescriber is not in agreement. The 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.

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

- the reasons for refusing to supply the medicine, including the benefits and risks involved with the MRP that has been identified, and
- recommended action to be taken by the patient to pursue safe and appropriate treatment in a timely manner, 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 unnecessary alarm for the patient.
Indirect dispensing

Indirect dispensing is the supply of medicines when there is no face-to-face contact with the patient by 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

The 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 responsible 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

All functions performed by either pharmacists or dispensary 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.

On supply of a medicine, 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.
Communication with prescribers

Pharmacists are encouraged to collaborate with the prescriber to optimise patient care.\(^3\)

Pharmacists should obtain the patient’s consent prior to contacting a prescriber. When communicating with a prescriber or other health professional, the pharmacist should specify their particular concern, provide supporting evidence and suggest appropriate alternatives.

Contact with the prescriber may be required if there is:\(^2\)
- doubt about the legality or validity of the prescription
- uncertainty about the prescriber’s intention
- clear potential for drug misadventure
- apparent over- or under-use of a medication
- doubt about the suitability of the medicine for the patient.

If the prescriber is not in agreement with the pharmacist’s concerns, pharmacists still have the right to refuse to supply medicines if they believe use is unsafe or inappropriate. The 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.\(^1\)

Where the pharmacist has refused 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 within the care of the patient.

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

Non-medical prescribing

Non-medical prescribers (e.g. optometrists, nurse practitioners, podiatrists) 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 and legislative requirements.
Pharmacist responsibilities

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.\(^1\) Collaboration does not alter the pharmacist’s personal accountability for the care provided to patients.\(^2\)

A pharmacist is responsible for\(^3,\(^4\)\):
- assessing the appropriateness of the medicines in relation to the medication history, with the responsibility to refuse supply if it is believed use will be unsafe or inappropriate
- 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 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.

A pharmacist must not delegate these professional responsibilities to a dispensary assistant/technician working under their supervision.

Supervision of dispensary assistants/technicians

The duties of dispensary assistants/technicians are defined by relevant legislation, and should be detailed in standard operating procedures.

A pharmacist has the ultimate responsibility for all activities undertaken by dispensary assistants/technicians. This includes ensuring that dispensary assistants/technicians:
- observe all patient confidentiality and privacy requirements
- 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/or experienced to perform in 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. Alternative ratios must be justifiable with consideration of the pharmacist’s workload and responsibilities.\(^4\)
Supervision of intern pharmacists

Intern pharmacists are provisionally registered pharmacists who may practice in accordance with supervised practice arrangements approved by the Pharmacy Board of Australia.

Supervision requirements include that the intern pharmacist be directly supervised by a pharmacist with general registration. Pharmacy premises must not have a total number of intern pharmacists that exceeds the total number of supervising pharmacists at any time. The supervising pharmacist has the ultimate responsibility for all activities undertaken by the intern pharmacist.

Security and access to patient records

A pharmacist must take reasonable steps to ensure patient records are protected and not subject to misuse, interference and loss, unauthorised access, modification or disclosure. In the dispensing process, this includes:

- maintaining a robust password for accessing dispensing software
- changing the password regularly
- implementing a robust process for sharing the password with dispensary assistants/technicians and interns
- closing patient records after use.

Access to the My Health Record system can be gained through conformant dispensing software. Delegation of access must be defined in the pharmacy’s My Health Record Security and Access Policy to ensure system security and patient privacy is maintained.

Non-pharmacist staff may access the My Health Record only if the pharmacist delegates them access according to the pharmacy’s My Health Record Security and Access Policy. Any access to the My Health Record system by non-pharmacist staff will be recorded in the access history of the patient’s My Health Record under the delegating pharmacist’s HPI-I.

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

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

There are a number of risks associated with the dispensing process that must be managed to ensure a consistent and high-quality level of care to patients. Risk management should focus on minimising or avoiding practices that are inconsistent with QUM principles.

Pharmacists should ensure that standard operating procedures outline the risk management plan to minimise the chance of dispensing errors and near misses (see Box 4).

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 quantity to be supplied, number of (and interval between) repeats. This means each repeat must be supplied on a separate occasion. This allows for review of therapy where necessary based on the patient’s response, and minimises the risk of medication misadventure or use of unnecessary medicines.

Note that where 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 annotating ‘Regulation 24’)
• prescribe the quantity and number of repeats needed on a private prescription.

Box 4. Dispensary risk management procedure

The following actions may be considered in a dispensary risk management plan:

• establishment of an efficient dispensary workflow to limit distractions and interruptions
• management of pharmacist and dispensary technician workload
• adjustment of the dispensary environment (e.g. including sufficient workbench space for prescription assembly, adequate lighting)
• monitoring the dispensing output and stock automated dispensing systems
• provision of regular dispensary training of all pharmacy staff
• use of barcode scanners to input prescription details and to verify medicine selection
• use of a container to keep all items together when dispensing multiple items for a patient
• establishment of an audit trail of pharmacist’s responsibilities and actions, e.g. initialling of dispensing label
• documentation and evaluation of identified issues, and appropriate response.

References: Sansom*; PDL**

*previously Regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960
It is important to be aware that, in endorsing a PBS prescription to dispense the original and all repeats at the same time (as described under the second dot point above), the prescriber will have considered that:

- the PBS-listed maximum quantity is insufficient for the treatment of the condition, and
- the medicine is being used for the treatment of a chronic illness, or the patient lives in an area remote from the nearest pharmacy, and
- it would cause great hardship if the patient was to collect repeat supplies on separate occasions.

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 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.

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

Where 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 restriction on multiple supply without appropriate clinical or practical need. Pharmacists should ensure all legislative requirements are adhered.

Barcode scanners
Pharmacists should use barcode scanners to minimise the risk of errors in the dispensing process, including incorrect:

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

However, barcode scanners are not a substitute for final checking processes, which are the pharmacist’s responsibility.

Workloads
Pharmacists must consider and manage their workload to ensure patient safety, reduce the risk of dispensing errors and promote personal health and wellbeing. It is suggested that an appropriate workload for an individual pharmacist is in the range of 150–200 items dispensed per day. However, 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 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 outlines maximum weekly hours for employees. It also provides guidance on determining whether additional hours are reasonable (for the employee).

Security of patient records and data breach processes
Pharmacy proprietors and pharmacists in charge of a dispensary or pharmacy department are responsible for ensuring electronic data and patient records are stored securely.

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 in error, this access should be noted in the patient history in the pharmacy’s dispensing software to enable follow up, if required.

A data breach occurs when personal information held by an organisation is lost or subjected to unauthorised access or disclosure. If a data breach occurs, pharmacists are required to notify affected individuals and the Office of the Australian Information Commissioner (OAIC) when a data breach is likely to result in serious harm to individuals whose personal information has been breached.
Complaint management

Under the *Australian Charter of Healthcare Rights*, patients have the right to comment on and complain about health care they have received. 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 is critical in supporting a pharmacist's response to a complaint.

In the event of an error, pharmacists should act in accordance with the *Australian Open Disclosure Framework*. 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.

In the event of unauthorised access to a patient's My Health Record by someone other than an employee of the pharmacy, the complaint is to be referred to management and/or the Office of the Australian Information Commissioner. 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 24 hours, 7 days) as soon as possible. Incidents may be related to safety, usability, technical, privacy and/or security issues. For more information on managing clinical incidents in the My Health Record System, see the latest version of PSA's *My Health Record Guidelines for Pharmacists*.

All registered practising pharmacists with general, limited or provisional registration must have professional indemnity insurance arrangements 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.
Appendix 1: Brand substitution of PBS medicines

Scope
This appendix is intended to provide guidance to pharmacists on brand substitution of generic or biosimilar medicines when dispensing a pharmaceutical benefit item (on a PBS or 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.79

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.

Products which are ‘a’-flagged have been determined by the Pharmaceutical Benefits Advisory Committee that they may be interchanged without any expected difference in clinical effect.20

Where brands are not ‘a’-flagged it is unknown whether or not they are equivalent or biosimilar. There may be several reasons for this, such as bioequivalence data not being considered necessary when the products were approved for marketing, or that advice or data have not been forthcoming from sponsors. This does not necessarily suggest a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.20

There are important considerations when the pharmacist is considering or undertaking brand substitution as outlined below.

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.

Where the prescriber has ordered a specific brand and marked on the prescription that substitution is disallowed, if 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 with appropriate explanation.

Where substitution has been disallowed (by the prescriber) but the pharmacist is unable to source the particular brand prescribed (e.g. 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 alternative 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 prior to brand 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.

Where the patient is offered a different brand or the patient enquires about alternative brands, information which 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 patients fully understand the substitution, and in particular, 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 which is out of stock at the suppliers. Where substitution is not disallowed by the prescriber, the pharmacist must provide thorough advice to the patient (including for example, differences in product presentation) whenever substitution occurs under
such circumstances.

Examples of when caution is required

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

Medicines with a narrow therapeutic index (critical dose medicines). Although any causal relationship between brand substitution of bioequivalent medicines and adverse outcomes remains unproven, special consideration is warranted with these medicines as 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.

Risk of confusion, anxiety or harm. Patients at risk 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 impact on 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, as well as advice on 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 they know how to use it correctly.

Refer also to Counselling in Dispensing Practice Guidelines.

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 QUM 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.

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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 the dispensing of items subsidised through the Pharmaceutical Benefits Scheme (PBS) or the Repatriation Pharmaceutical Benefits Scheme (RPBS). However, PBS (or RPBS) dispensing can involve extended or alternative supply arrangements, and there are also other (non-PBS) supply arrangements. Some examples are provided below (the list is not exhaustive).

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 and clozapine) – see www.pbs.gov.au/info/browse/section-100/highly-specialised-drugs
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
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 chronic disease 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

Dextropropoxyphene
The registration and supply of dextropropoxyphene-containing products, Di-Gesic and Doloxene, are subject to specific conditions – for more information, see:
• www.tga.gov.au/alert/dextropropoxyphene-questions-and-answers
To view a copy of the Prescriber confirmation form, see https://aspenpharmacare.box.com/shared/static/ltwt13v07nmsadflh26qb.pdf

Accessing unapproved products
• Special Access Scheme – this arrangement provides patient access to medicines that are not on the Australian Register of Therapeutic Goods; see www.tga.gov.au/form/special-access-scheme
• Clinical trials – see https://www.tga.gov.au/clinical-trials

Medicinal cannabis
A regulatory framework to allow Australian patients to legally access medicinal cannabis products has been developed. Further advice is available from https://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: Counselling with Consumer Medicine Information leaflets

Scope

This appendix is intended to provide guidance to pharmacists on counselling with Consumer Medicine 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 in accordance with requirements set out in the Therapeutic Goods Regulations 1990.23

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, pads of leaflets and online24 as well as integrated with dispensing software.

Supporting patients through the provision of CMI

CMI leaflets can be used to provide medicine 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.26-28 Patients appreciate receiving written or verbal information about medicines they are taking and there are benefits in providing information, in particular, written medicine information.26, 27, 28 Using CMI leaflets in a variety of pharmacy settings (e.g. community,29 hospital,30 and transitions of care31) is influenced by many factors including the patient’s cultural and linguistic preferences and environment.

Barriers around CMI leaflets are often mentioned, including for example, that they are too long, they may not cater for certain population groups (e.g. children or people with a disability), and not all leaflets are 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 rely on unverified information sources.

It has been reported that patient factors such as disease state, coping style, health literacy levels and occupation influence the patient’s interest in reading and seeking written medicines information and therefore, pharmacists have a role in tailoring the counselling they provide to better meet the patient’s needs.27,28

The level of detail and nature of information contained 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.32,33

Information about side effects is reported to be of key importance to patients.34 It is important for pharmacists to discuss side effects in the right context and provide support rather than avoid the topic. Evidence around the relationship between patients reading about adverse effects in written medicine information and subsequently ceasing or changing medication is reportedly contradictory.35 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 (TGA) requires that for medicines that have CMI leaflets, they 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.24 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 or replacement 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 help increase patient knowledge, facilitate the appropriate use of medicines and can thereby enhance therapeutic outcomes. They can also assist to minimise the potential for adverse drug reactions through inappropriate use, and help patients to monitor any adverse effects and to report them to a health professional in a timely manner.
During a discussion with a patient, a pharmacist may:

- highlight sections of the CMI leaflets that are particularly relevant to the patient
- use the CMI leaflet to facilitate patient engagement and encourage the patient to read and seek clarification as necessary, and ensure 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 judgment and discretion in each situation to ensure that they are providing balanced information to the patient.\textsuperscript{18}

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 those additions. CMI leaflets must not otherwise be altered or abbreviated in any way by the pharmacist as 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 to the current version of the CMI leaflet each time a product is dispensed.

CMI leaflets have a role in assisting pharmacists facilitate QUM including\textsuperscript{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 providing regular reinforcement of information may be required (e.g. the medication is cytotoxic, teratogenic, or there are major contraindications to the use of a medicine)
- 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 may already be familiar with and well informed about their medicine.

Pharmacists may need to specifically tailor the information contained in the CMI leaflet. Pharmacists should consider this when dispensing high-risk medicines or in other situations where the provision of a CMI leaflet may be important, for example\textsuperscript{4}:

- medicines which 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 on the Australian Register of Therapeutic Goods (ARTG) is described as being prescribed ‘off-label’ when its intended use is not included, or disclaimed, in the approved PI or CMI leaflet including use:

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

Off-label use is permitted under certain, clinically appropriate circumstances and may be encountered more frequently where specialist prescribers are involved in the health care of the patient including 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.\textsuperscript{36,37} Exceptional use may be justified by individual clinical circumstances.\textsuperscript{36}

The prescriber may not always communicate off-label prescribing. Professional judgement may be required based on information on the dosage regimen, patient’s history or presentation of a non-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\textsuperscript{38}:

- confirm the use of the medicine (as there may be 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 if they experience any adverse effects
- provide information about the cost of the medicine
- make a professional judgment 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 and 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 judgment, they withhold a CMI leaflet from the patient.
References

41. Pharmaceutical Society of Australia. Guidelines for pharmacists performing clinical interventions. 2018