

# CALs in practice

The Cautionary Advisory Labels (CALs) have become an essential part of Australian pharmacy practice. CALs are a valuable tool for helping pharmacists to fulfil their legal and professional obligations, promote quality use of medicines, and provide optimal outcomes for consumers. This article reinforces the importance of using CALs in your practice, provides insight into their development and advises on their appropriate use. Useful information about CALs can be found in the *Australian Pharmaceutical Formulary and Handbook 21st edition (APF21)*.

## Are you complying with your legal and professional obligations?

In 2007 the Minister for Health and Ageing made a Determination under the National Health Act 1953 setting out conditions that apply to approved pharmacists. These conditions include the following statement:

'An approved pharmacist must, in dispensing prescriptions for pharmaceutical benefits and in supplying pharmaceutical benefits:

- comply with the Pharmaceutical Society of Australia's *Code of Professional Conduct*
- comply with the Pharmaceutical Society of Australia's *Professional Practice Standards*.'

**Obligation 4.3** of the PSA's *Code of Professional Conduct* states:

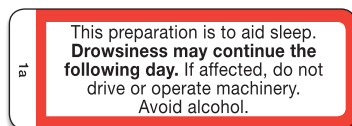
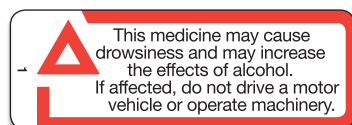
'A pharmacist shall provide professional advice and counselling at every appropriate opportunity to ensure the patient and/or carer are sufficiently informed about the safe and effective use of their medications and to achieve optimal outcomes.'

**Criterion 5.9** of the PSA's *Professional Practice Standards* states:

'Consumers are given adequate additional instructions about using dispensed medicines safely and storing them properly.'

Indicator 1: Uses appropriate ancillary labels on dispensed medicines as recommended in the *Australian Pharmaceutical Formulary and Handbook*.'

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) includes in Appendix K a list of drugs required to be labelled with a specifically-worded sedation warning as provided in CAL 1 or 1a.



In addition, specific state and territory legislation may have other requirements regarding labelling of medicines. The *Professional Practice Standards* states 'It is assumed that pharmacists will comply with required Commonwealth/State/Territory legislation in the provision of all pharmacy services'. Pharmacists should therefore familiarise themselves with their individual state/territory labelling requirements as part of their professional obligations.

## Are you using CALs to support counselling?

Appropriate counselling helps to ensure that medicines have the intended therapeutic effect, and minimises the risk of preventable



adverse effects. This involves both verbal communication with consumers about the safe and effective use of their medicines, and reinforcement of this communication with written information (e.g. Consumer Medicine Information (CMI), CALs and Pharmacy Self Care fact cards).

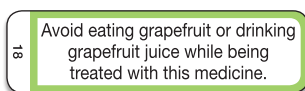
CALs provide pharmacists with a convenient and effective way to support their counselling with written information in the form of statements which are affixed to the primary container, thereby acting as a continual reminder to patients. They are therefore a valuable tool for helping pharmacists to fulfil their legal and professional obligations, promote quality use of medicines, and provide optimal outcomes for consumers.

## Are you using CALs correctly?

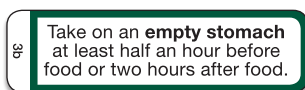
Information on the correct use of CALs can be found in *APF21*. The *Counselling and cautionary advisory labels for medicines* section of *APF21* includes a sample of each CAL to assist with identification of the correct label to be used. Each

label is accompanied by information about what types of medicines the label should be used on, why its use is recommended, and how it is to be applied in practice. There are two main types of CAL:

- Ancillary labels which are divided into two categories:
  - those that warn against undesirable effects, including interactions with other medicines or foods



- those that are designed to optimise efficacy in the use of the medicine.



- Additional instructions which provide information about the appropriate use or storage of the medicine.



The section also includes a list of medicines requiring cautionary advisory labels and the CALs applicable to each medicine.

## Are you using currently approved CALs?

CALs are reviewed and updated with each new edition of the *APF*. This review is carried out by a CAL Working Group which includes pharmacists from all areas of practice, as well as external stakeholders such as Vision Australia to assist in meeting the needs of the elderly and vision impaired. Their recommendations are considered and approved by the *APF* Editorial Board.

In 2006, PSA carried out a major review and update of the CAL standards and specifications, with the aims of reducing the risk of using incorrect labels and promoting consistency in the use of CALs across Australian pharmacies. The CAL Working Group also ensured that the labels were consistent with the SUSDR. To ensure optimum legibility

for vision impaired consumers, the design and specifications of the labels were based on advice and information from Vision Australia, including their *Guidelines for producing readable text*. Criteria addressed in these guidelines include contrast, colours, type size, typefaces, type styles and spacing.

The updated CAL specifications included:

- Black lettering on a white background for ease of consumer readability.
- Each label was to have a unique colour to avoid confusion with other pharmaceutical labels.
- Label sizes were reviewed to ensure that they were large enough for the print to be clearly legible. Labels 1 and 1a were made larger in order to maximise font size.
- Label wording was reviewed for clarity and conciseness.
- Typeface was chosen for maximum readability.
- Label identification number was to be located in a consistent place.

The ultimate aim was to achieve safer use of medicines by consumers. In Emeritus Professor Lloyd Sansom's words 'the labels are for the consumer – so that the consumer has a better understanding of the medication they are using'. To promote optimal safety and outcomes for consumers and avoid confusion, previous versions of CALs should not be used. All pharmacies should ensure that they are using the currently approved CALs.

In some circumstances there may be a need for a label that does not form part of the approved CALs (e.g. the use of a label to warn that a drug is a cytotoxic). However, where a label is required that is available as a CAL, then the approved CAL should be used, as they have undergone rigorous review and development and are best suited to meet the needs of consumers.

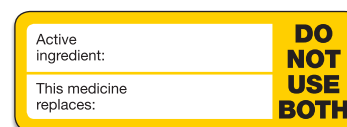
## Are you aware of recent changes to CALs?

While most of the CALs in *APF21* are unchanged from the previous edition, three changes have been made:

- The wording of **Label 11** has been reviewed to improve clarity and ease of understanding by consumers.



- A new label (**15b**) has been introduced as an alternative to label 15a. It was designed as part of the National Prescribing Service *Generic medicines are an equal choice* campaign and provides a space for the pharmacist to write the name of the medicine's active ingredient. This allows consumers to be confident that they are receiving the correct medicine and minimises the risk that they will unknowingly be taking more than one brand of the same medicine.



- The wording of **Label E** has been changed from 7 to 14 days, to bring it in line with current therapeutic recommendations.



## Any questions?

If you have any questions specifically regarding the use of CALs in your practice please email to [APF21@psa.org.au](mailto:APF21@psa.org.au)

### Bibliography and useful resources

Sansom L (ed). Australian Pharmaceutical Formulary and Handbook, 21st Ed. Canberra: Pharmaceutical Society of Australia, 2009.

Code of Professional Conduct. Pharmaceutical Society of Australia. At: [www.psa.org.au/site.php?id=628](http://www.psa.org.au/site.php?id=628).

Professional Practice Standards. Version 3, 2006. Pharmaceutical Society of Australia. At: [www.psa.org.au/site.php?id=843](http://www.psa.org.au/site.php?id=843).

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007. National Health Act 1953. At: [www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/5390B640E5346B53CA25734100173F03?OpenDocument](http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/5390B640E5346B53CA25734100173F03?OpenDocument).

Standard for the Uniform Scheduling of Drugs and Poisons, No. 24. Commonwealth of Australia, 2009. At: [www.tga.gov.au/ndpsc/susdp.htm#susdp](http://www.tga.gov.au/ndpsc/susdp.htm#susdp) OR [www.comlaw.gov.au/comlaw/%5Cmanagement.nsf/lookupindexpagesbyid/IP200943235?OpenDocument](http://www.comlaw.gov.au/comlaw/%5Cmanagement.nsf/lookupindexpagesbyid/IP200943235?OpenDocument).

Guidelines for producing readable text. Vision Australia. At: [www.visionaustralia.org.au/info.aspx?page=1845](http://www.visionaustralia.org.au/info.aspx?page=1845)

It's about QUM and the consumer. Aust Pharm. Aug 2006; 25(8):597–8.

Health Consumers Rely on Labels. PSA information pamphlet. Pharmaceutical Society of Australia, 2006.

NPS media release: Generic medicines ancillary label here to stay. National Prescribing Service, Jan 2009.

Low J, Hattingh L, Forrester K. Australian pharmacy law and practice. Elsevier Australia 2010.