Cautionary Advisory Labels in practice

Cautionary Advisory Labels (CALS) produced by the Pharmaceutical Society of Australia (PSA) are essential consumer resources that promote quality use of medicines.

Since their introduction in 1974, CALs have been a convenient and effective way to supplement verbal counselling and are a valuable tool for helping pharmacists to fulfil their legal and professional obligations. This article provides an update on the optimal use of CALs.

Further information about CALs can be found in the 23rd edition of the Australian Pharmaceutical Formulary and Handbook (APF23).³

Legal and professional obligations

The Poisons Standard⁴ outlines the Commonwealth legislative requirements for the labelling of drugs and poisons. Appendix K of the Poisons Standard contains a list of drugs that are legally required to be labelled with a specific worded sedation warning (as used in CALs 1 and 1a). Appendix L of the Poisons Standard contains a list of drugs that are legally required to be labelled with specifically worded warnings about the risk of teratogenicity associated with the use of the medicine in pregnancy (CAL P).

Specific state or territory legislation may impose additional labelling requirements, and pharmacists must comply with both Commonwealth and state/territory legislation when labelling medicines.

The routine use of CALs other than those that are legally required is recommended. However, pharmacists may use their knowledge and professional judgement to decide which of the recommended CALs are most appropriate for a specific consumer or circumstance.

The Guidelines for dispensing of medicines¹ and the Professional Practice Standards³ outline the professional obligations of pharmacists when dispensing and counselling. Providing consumers with additional instructions about the safe and correct use and storage of dispensed medicines is a key professional obligation. CALs offer a convenient and effective means of supplementing verbal instructions.

Supporting verbal counselling

The aim of counselling is to provide consumers with a good knowledge and understanding of their medicines. Appropriate counselling helps to ensure that the intended therapeutic effect is achieved and the risk of adverse effects is minimised. Counselling involves communicating verbally with consumers about the safe and effective use of their medicines, and reinforcing this communication with written information.

Written information provided without verbal explanation can be misleading or confusing for some consumers. CALs are intended to reinforce rather than replace verbal counselling. Pharmacists should confirm that consumers (particularly those with limited literacy) understand the meaning of the CALs that are applied to their medicines.

Correct use of CALs

APF23 contains explanatory information about current CAL recommendations, including the types of medicines each label is used for, why the CAL is recommended, and how it is used in practice. There are two types of CALs:

- Ancillary labels (identified by numbers 1–24) are used to warn consumers about undesirable effects (including interactions with other medicines or foods) or advise consumers on the safe and correct use of the medicine, in order to optimise health outcomes. Ancillary labels should be attached to the immediate container of the dispensed medicine wherever possible.

- Additional instructions (identified by letters A–P) provide information about the appropriate use or storage of the medicine. They can be attached to the primary medicine container or incorporated into the main dispensing label. Exceptions are CAL D and P, which are not produced as ‘stand-alone’ labels and are designed to be incorporated into the main dispensing label. Pharmacists can use their professional judgement to decide the most appropriate way to display additional instructions.

Pharmacists have a professional responsibility to use approved CALs in a manner consistent with the CAL recommendations published in the current edition of APF. Pharmacy dispensing software prompts can be a helpful reminder of the appropriate CALs to use for particular medicines at the point of dispensing. Pharmacists need to be satisfied that the recommendations included in dispensing software prompts are consistent with the recommendations published in the current edition of APF in both wording and application.

CAL review process

PSA maintains ownership of the CALs and CAL recommendations, which are published in each new edition of APF. APF23 contains the current CAL recommendations, as approved by the
APF23 Editorial Board. The CAL Working Group provides recommendations to the APF Editorial Board about CALs and the assignments of CALs to new and existing medicines. In making CAL recommendations, the CAL Working Group considers current evidence from published literature, approved product information, consumer medicine information, current clinical best-practice, statutory requirements in the Poisons Standard® and feedback from external stakeholders. The design and specifications of the labels (including suitable colours, contrast, type size, typefaces, type styles and spacing) are based on advice and information from Vision Australia, to address the needs of consumers with vision impairment.

Other supplementary labels that are not approved by the APF Editorial Board may be available. Approved CALs have undergone rigorous review and development to ensure they are best suited to meet the needs of consumers. This also reduces the risk of incorrect label use, ensures compliance with legislative requirements in the Poisons Standard, and promotes consistent use of CALs in Australian pharmacies.

The CALs and CAL recommendations approved by the APF Editorial Board may not be reproduced without obtaining explicit permission from PSA. Requests for permission to reproduce CAL content and a full set of CAL specifications can be directed to PSA on 02 6283 4777.

Changes to CALs

The new edition of APF contains a number of significant changes to the CAL recommendations. These changes may represent a therapeutic protocol change or a clarification recommended by the CAL Working Group to assist consumers. Pharmacists can review these changes by referring to the ‘Recommended cautionary advisory labels for medicines’ table in APF23 and updates available on the PSA website. Pharmacists should ensure they are using the currently approved CALs, to avoid confusion and promote optimal safety and health outcomes for consumers.

**Summary of new labels**

- **Label 4b** is for use on medicines that are susceptible to reduced absorption when gastric pH is raised (e.g. itraconazole).
- **Label 23** is for use on medicines that have been extemporaneously prepared.
- **Label 24** is for use on non-prescription analgesic medicines containing codeine or non-prescription dihydrocodeine products.

**Summary of revised labels**

- **Label 4** has been revised to reflect the two different mechanisms that are involved in interactions between medicines and metallic ions, such as calcium (chelation and raised pH). Label 4a is used for medicines that form chelates in the gastrointestinal tract (e.g. doxycycline).

- **Label 10b** has been revised to include anti-inflammatories. Label 10b is for use on oral anticoagulants, which should not be taken with aspirin or non-steroidal anti-inflammatories.

- **Label 1** has been revised to account for emerging evidence that juices other than grapefruit juice can interact with some medicines. It is still relevant for use on monoamine oxidase inhibitors, but can now also be used on medicines that have been shown to interact with juices other than grapefruit juice (e.g. atenolol).

**A significant change in APF23 relates to the expansion of the use of label 21. APF23 contains a list of hazardous medicines that are considered to pose a health and safety risk to people handling the medicine (e.g. carers, family members, healthcare professionals) as a result of unintended exposure. Medicines included in this list meet one or more of the following criteria:  
- cytotoxic  
- designated as pregnancy category X or D  
- reported to pose a risk to patients or carers through inappropriate handling.**

It is recommended that medicines included in this list are labelled with label 21 and label A (oral products). Explanatory notes for label 21 in APF23 provide further details about the special handling requirements for these medicines.

APF23 contains further information about the application and correct use of each CAL. Questions regarding the use of CALs in your practice can be sent to: apf@psa.org.au.

Further reading


References