

# Counselling and cautionary advisory labels for medicines

## Counselling

Pharmacists must offer counselling to the patient at every opportunity. Appropriate counselling ensures that medication has the desired therapeutic effect and that the incidence of preventable adverse effects is minimised. It is the pharmacist's responsibility to promote the quality use of medicines by ensuring that the patient receives the required information. Counselling involves the communication of information that would encourage this outcome.


Counselling should be reinforced with written instructions, including labels attached to the immediate container of dispensed medicines (where practical), as well as Consumer Medicine Information. Written instructions do not, however, replace verbal counselling.

Counselling for repeat prescriptions is also important as it enables the pharmacist to determine by appropriate questioning and information exchange whether a patient is experiencing adverse reactions or has other concerns relating to their medicine.

Whenever possible, oral medications should be taken with a glass of water while the patient is in an upright position.

## Cautionary advisory labels

The most common issues requiring written reinforcement of counselling are incorporated in the cautionary advisory labels (CALs) as either 'Ancillary labels' or 'Additional instructions'. Samples of each CAL are included in this section to assist with identification of the correct label to be used. These CALs were approved by the APF Editorial Board and, while there may be other appropriate supplementary labels in use, they are not approved by the Editorial Board. A full set of specifications suitable for printing companies can be obtained by contacting the PSA directly on 02 6283 4777.

Pharmacists should note that changes to CALs from the previous edition are marked using . These changes may represent a therapeutic protocol change or a clarification recommended by the CAL Working Group to assist consumers.

To avoid confusion, previous versions of CALs should not be used.

## Medicines requiring labels

Table A.1 lists medicines for which CALs are required. Medicines are considered for inclusion in the list by the CAL Working Group of the APF Editorial Board if they meet at least three of the following criteria:

- They are medicines in clinical use in Australia.
- They are medicines registered in Australia since the previous edition of the *Australian Pharmaceutical Formulary and Handbook*.
- They are taken orally or routinely self-administered by injection—excluding those administered within a health care facility.
- The medicine is considered by the CAL Working Group to warrant additional information to achieve quality use of medicines principles—e.g. transdermal products.

Medicines that may not be currently registered in Australia but that are likely to be available in the near future are also included.

In Table A.1 pharmacists should refer to both individual medicines listed for combination products.

## Labelling considerations

The CALs for each medicine are determined by considering:

- evidence from the published literature—including the approved Product Information and Consumer Medicine Information
- statutory requirements included in Appendix K of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) by the National Drugs and Poisons Schedule Committee of the Therapeutic Goods Administration.

It may be appropriate for pharmacists to add the designated label(s) to non-prescription products if such information is not provided on the immediate container, package label, or Product Information in the package.

In general, pharmacists may use their knowledge and professional discretion in deciding whether to omit one or more ancillary labels. The exception is medicines for which laws require that certain advisory labels be attached—that is, namely labels 1 and 1a for medicines listed in Appendix K of the SUSDP.<sup>a</sup> The prescriber may recommend that a CAL not be used, but in this

a. The Australian Pharmaceutical Formulary and Handbook does not include those drugs listed in Appendix K that are no longer available in Australia or are administered only by a health professional.