

# Issues to consider when providing medicine information

By Dr Laetitia Hattingh

**Pharmacists are the medication experts and have a legal and professional obligation to provide medicine information to patients. However, the provision of information may not be necessary each time a medicine is supplied or dispensed and each individual patient's or carer's needs should be considered. Professional judgment therefore has to be applied regarding the individual's requirements and the information should be tailored around their specific needs.**

## Written medicines information

A Consumer Medicine Information (CMI) leaflet is a useful tool to be used when informing patients or carers about medicines. The importance of issuing CMI leaflets is reinforced by the *Guidelines for pharmacists: Consumer Medicine Information and the pharmacist* which recommend the provision of leaflets in specific instances, namely:<sup>1</sup>

- when a medicine is first provided to the patient;
- when brand substitution occurs and it is deemed appropriate;
- when the dosage form has been changed;
- with each supply of medicine for which regular reinforcement of information may be required;
- at the request of the patient/carer;
- when the patient has special needs;
- at regular intervals for medicines used for long term; and
- when the pharmacist has received advice that a sponsor has made significant changes to the CMI.

While CMIs do not replace counselling or reduce pharmacists' duty to advise patients about medicines, they should be used to support verbal counselling. Pharmacists are strongly advised against withholding CMI leaflets.

CMIs are brand specific, must be in a specified format and must include specific information

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in accordance with requirements set out in the *Therapeutic Goods Regulations 1990* (Cth).<sup>2</sup> During counselling, pharmacists may highlight parts which are particularly relevant to the patient and annotate the CMI with additional information. However, CMIs may not be altered or abbreviated as they are the official approved product documents.

In practice there could be instances when pharmacists may need to develop written medicine information resources themselves, for example during extemporaneous dispensing. In those cases it is important to explain to the patient or carer that the written information is not a CMI or is not replacing a CMI as a pharmacist could be open to a claim of negligence if a patient experiences a side-effect that is not covered in the written information. An example of such a case is the United States case of *Cottam v CVS Pharmacy* (2002).<sup>3</sup> In this case the Supreme Court found the pharmacy 51% negligent for not warning a patient of priapism as a potential side-effect of the antidepressant trazodone; the patient was left permanently impotent as a result of using the trazodone. The court found that the pharmacy voluntarily assumed a duty to provide information, advice and warnings to a patient as it was the pharmacy's normal practice to issue a 'long form' list of side-effects when a medicine was dispensed for the first time. By giving out a list of information as part of the pharmacy's normal practice the pharmacy voluntarily assumed a duty to warn and in so doing had to perform that duty with due care. The court found that where the information provided could be reasonably understood by the patient as a complete list

of side-effects, it is appropriate to impose the duty to warn as to all potential side effects.

## Benefits and risks

Patients have a right to make their own medication management decisions but in order for them to do so they need sufficient information about treatment options and the likely result if treatment is not followed. Pharmacists should facilitate the patient or carer's understanding of their medicines and provide information about individual medicines in the context of the patient's needs, considering their disease conditions, social situation and other medicines.

It is not possible to predict outcomes or assess risks with certainty and pharmacists need to use professional judgment in explaining this to patients. In the landmark case of *Rogers v Whitaker* (1992)<sup>4</sup> the Australian High Court made it clear that the information a professional ought to supply to a patient should be patient-focused rather than health practitioner-focused. The majority judgement of this case was based on the opinion that as far as technical blunders are concerned, the practitioner-patient relationship requires little contribution from the patient, as the practitioner should perform at a level requiring professional knowledge and skill. However, where allegations involve the provision of information and advice, the practitioner should provide the appropriate amount and level of information necessary for the patient to reach a decision. Health professionals therefore need to use their judgement in deciding what information to provide to patients and make an assessment as to whether the individual patient would be likely to attach significance to it.

## Key points

Pharmacists need to counsel patients daily about prescribed and non-prescription medicines and inform patients of the benefits and relevant side effects as a result of taking the medication.

Providing medicine information is a skill and requires the application of professional judgement to ensure that the information provided is balanced and at an appropriate level for patients to understand to facilitate their decision-making.

## References

1. Pharmaceutical Society of Australia. Guidelines for pharmacists: Consumer Medicine Information and the pharmacist. 2007.
2. Therapeutic Goods Regulations 1990 (Cth).
3. *Cottam v CVS Pharmacy* (2002) 436 Mass 316, 764, NE 2d 814.
4. *Rogers v Whitaker* (1992) 175 CLR 479.