SA Palliative Care Community Pharmacy Update

A joint initiative of South Australian Palliative Care Services

The TGA registers medications for specific indications. Prescribing medications outside of this registration is off-label and pharmacists should be aware of the principles of this use and its practical implications.

Off-Label Prescribing

A medication used for a different indication, at a different dose, via an alternate route of administration or for a patient of an age or gender outside the TGA registered use is considered offlabel. This excludes unlicensed use where the medication is not registered in Australia.

While not limited to palliative care, offlabel prescribing is more widespread in this area due to a unique patient population where clinical trials are less common and the data available limited.

Assessing appropriateness of offlabel medicines use

Med J Aust 2006; 185(10):544-548.

Will this medicine be used according to a registered indication, age, dose and route?

NO

(ie, off-label use of registered medicine for different indication, age, dose or route)

YES

Follow the usual process for consent to therapy

Is there high-quality evidence supporting its use?

Evaluate published research evidence about safety and efficacy

YES Routine off-label use

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Off-label use generally NOT justified. but may be appropriate

- Follow the usual process for consent to therapy
- Discuss additional issues of off-label status
- In some cases, it may be appropriate to document the and/or to obtain vritten informed consent

Use within formal research

- approved by institutional research
- written informed consent obtained

OR

Exceptional use in an individual patient IF:

- · there is a serious underlying disease or condition; AND
- there is some evidence to support potential beneficial effect; AND
- · potential benefits outweigh potential risks; AND
- standard therapy has been trialled or is inappropriate; AND
- use has been approved by institutional drug committee; AND
- · written informed consent obtained

The use of TGA approved medications should be considered prior to considering off-label prescribing. TGA approved medications may be unsuitable or poorly tolerated by the patient making off-label prescribing an appropriate option.

In general, the benefit to risk ratio should be considered in the context of amount and quality of evidence available. In some cases, the prescriber should seek external approval and written informed consent prior to use.

Implications for Pharmacists

Medications prescribed off-label may be dispensed by pharmacists.

CMIs only include information about TGA approved use and additional information and counselling may be required.

Pharmacists should also monitor for adverse effects which may emerge when medicines are used off-label.

Useful resources

- > Rethinking medicines decision-making in Australian Hospitals. Guiding principles for the quality use of off-label medicines. Council of Australian Therapeutic Advisory Groups; 2013.
- Gazarian M, Kelly M, et al. Off-label use of medicines: consensus recommendations for evaluating appropriateness. Med J Aust 2006; 185(10):544-548.
- > Therapeutic Guidelines: Palliative Care, 3rd Ed. Therapeutic Guidelines Limited, 2010.

For more information

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This update is intended to provide practical up to date and factual information relating to pharmacy and medicines management in the setting of Palliative Care and is based on critical review of available evidence. Individual patient circumstances must be considered when applying this information. Please feel free to distribute this update further to interested colleagues.