

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 off-label. This excludes unlicensed use where the medication is not registered in Australia.

While not limited to palliative care, off-label 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 off-label medicines use

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



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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