



Australian Government
Department of Health
Therapeutic Goods Administration

Mr Josh Munro
Coroners Registrar
Coroners Court of Victoria
Level 11, 222 Exhibition Street
MELBOURNE 3000



Our Reference: R14/884218

Dear Mr Munro

Subject: Response to recommendation made by the coroner to the TGA in reference to Caroline C Webster, Court Ref: COR 2012 001388

Thank you for the opportunity to respond to the coroner's recommendation to the Therapeutic Goods Administration (TGA) in the case of Caroline C Webster.

The TGA will implement the coroner's recommendation by publishing the attached article regarding propranolol in the October 2014 issue of its bi-monthly drug safety bulletin, *Medicines Safety Update (MSU)*.

The article advises health professionals to exercise caution when prescribing propranolol to patients suspected of being at risk of self-harm, particularly by overdose. The TGA recommends that health professionals consider providing prescriptions for smaller quantities or to make other arrangements to reduce the amount of propranolol to which the patient has access at one time.

However, the article does not advise health professionals to consider prescribing at-risk patients an alternative medicine that is safer in overdose, as recommended by the coroner. This decision has been based on the TGA's expert view that alternative treatments will generally have a similar overdose risk profile.

MSU is distributed to health professionals around Australia within the NPS MedicineWise's *Australian Prescriber (AP)* publication and is also published electronically on the TGA and AP websites.

Yours sincerely

Prof John Skerritt
National Manager
Therapeutic Goods Administration

16 September 2014

Propranolol – prescribing to patients who may be at risk of self-harm

A recent case investigated by the Coroners Court of Victoria has prompted a warning regarding prescribing propranolol for patients who are suspected of being at risk of self-harm.

Propranolol is a beta-adrenoreceptor blocking drug which has a number of indications, the most common of which are:

- angina pectoris
- hypertension
- prevention of migraine
- essential tremor, including familial and senile tremor
- management of some cardiac dysrhythmias.

Propranolol is available in Australia in 100-tablet pack sizes of 10 mg and 40 mg tablets, as well as a 50-tablet pack of 160 mg tablets. If repeats are provided with a prescription for propranolol, the patient could accumulate a large number of tablets at one time.

The coroner recommended that the TGA advise health professionals to exercise caution when prescribing propranolol for patients suspected of being at risk of self-harm, particularly by overdose. Overdosage of propranolol can result in bradycardia, hypotension, bronchospasm and/or acute cardiac failure.

If propranolol is prescribed, consider providing prescriptions for smaller quantities or make other arrangements to reduce the amount of the drug that the patient has access to at one time.

Adverse events

From 1972 to 1 July 2014, the TGA has received 829 reports of adverse events involving propranolol. Of these reports, five involved overdose and/or intentional overdose. Two of these cases resulted in the patient's death.

Health professionals are encouraged to report to the TGA all suspected adverse events relating to propranolol, particularly if they involve overdose and potential self-harm.