TGA in Australia cancels and recalls cough medicines containing pholcodine

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Following a safety investigation by the Therapeutic Goods Administration (TGA), 55 products containing pholcodine are being canceled from the Australian Register of Therapeutic Goods and those

currently on pharmacy shelves are being recalled from pharmacies.

The cancelation and recall actions are being taken because of a link between pholcodine-containing medicines and an increased risk of anaphylactic reactions (a sudden, severe and life-threatening allergic reaction) to certain medicines used as muscle relaxants during general anesthesia (called neuromuscular blocking agents).

Pholcodine has been used in a wide range of over the counter pharmacy medicines to treat non-productive (dry) cough, particularly in syrups and lozenges. It is also used in combination with other medicines in products that treat the symptoms of cold and flu.

TGA Head Adjunct Professor John Skerritt said, "It is difficult to reliably predict who may be at risk of anaphylaxis during anesthesia and some patients may not know if they have taken pholcodine medicines recently."

"Some patients undergoing emergency surgery may not be in a position to talk to their anesthetist at all. In addition, while surgical facilities may ask about which prescription medicines a patient is taking, they may not ask about over the counter products."

"Fortunately, safer alternatives to treat a dry cough are available and consumers should ask their doctor or pharmacist for advice. I urge consumers to check if any of your over-the-counter cold and flu medicines contain pholcodine and, if they do, ask your doctor or pharmacist to suggest an alternative treatment."

"If you will need general anesthesia and have taken pholcodine in the past 12 months, I advise you to tell your health professional. Health professionals should also check whether patients scheduled to undergo general anesthesia have used pholcodine in the previous 12 months."

The TGA's investigation followed a review by the European Medicines Agency (EMA) recommending the withdrawal of marketing authorizations for these products in Europe. The European findings were supported by a Western Australian study which also showed that pholcodine was a risk factor. Up to 9 February this year, the TGA has also received 50 reports of Australian cases of suspected pholcodine-related anaphylactic reactions to neuromuscular blockers, including one fatality.

Provided by Dept of Health and Aged Care, Therapeutic Goods Administration (TGA)