

9 March 2023



Chris James
Medsafe Group Manager
PO Box 5013
Wellington 6140
committees@health.govt.nz

Dear Chris James

Re: Pholcodine-containing medicines

We, the New Zealand Society of Anaesthetists (NZSA), implore Medsafe to withdraw pholcodine-containing medicines from New Zealand due to the associated risk of anaphylactic reaction to neuromuscular blocking agents (NMBAs) used during general anaesthesia.

The NZSA is a professional medical society which represents over 800 Anaesthetists and Specialist Pain Medicine Physicians (SPMP) in New Zealand. Our members include Specialist and Trainee Anaesthetists and SPMPs in public and private practice. Our key roles are advocacy, facilitating and promoting education, and strengthening networks of anaesthetists nationwide.

In line with the actions of the Australian Therapeutic Goods Administration (TGA) and The National Agency for the Safety of Medicines and Health Products in France, withdrawing pholcodine-containing medicines will follow the recommendations of the European Medicines Agency (EMA). Their recommendation is that *healthcare professionals should no longer prescribe or dispense pholcodine-containing medicines and should consider appropriate treatment alternatives*. Included in their review was an evaluation of the ALPHO study¹ that demonstrates a significant risk of NMBA-related perioperative anaphylaxis in patients exposed to pholcodine consumption 12 months prior to exposure to NMBAs.

In addition, the decision of the TGA takes into consideration a Western Australian study (Relationship of perioperative anaphylaxis to neuromuscular blocking agents, obesity, and pholcodine consumption: a case-control study)² with outcomes that support the conclusion of the ALPHO study.

Anaphylaxis is a life-threatening condition that comes at a great cost when it occurs. Both to the patient and the health care system. We wish to reshare an excerpt below taken from a letter the NZSA wrote to Medsafe in 2018 following a meeting to consider reclassifying pholcodine.

As Anaesthetists one of the most challenging aspects of our jobs is when presented with an idiosyncratic response that is unexpected, such as anaphylaxis. This life-threatening

condition comes at great cost when it occurs; cost to the patient, who may die, but also to their time as their elective surgery may have to be cancelled; cost to the health system with unanticipated admissions to the Intensive Care Unit (which may in turn cause the cancellation of other operations because of limited bed spaces in the ICU), and then the further costs of follow up clinic for anaesthetic allergy testing.

Anaphylaxis is an extremely stressful crisis which primarily affects the patient, but also the entire operating team who are involved in the treatment which may include the need for cardiopulmonary resuscitation with chest compressions as well as adrenaline infusions and large amounts of IV fluid to combat the generalised capillary leak. Patients may require days of intensive care treatment as the swelling subsides. It is an extremely anxiety-provoking event for a patient, and often compounded by the required six-week wait that precedes allergy testing. Especially so if the patient must undergo urgent or repeat surgery during that time when they are not sure what compound caused the anaphylaxis.

This new information and the actions of these international bodies demonstrate the significant and potentially life-threatening harm this medicine poses to the population of New Zealand. Whilst anaphylaxis may be rarer, the high cost of its occurrence far outweighs the limited and possibly inconsequential benefit to an individual with an irritating cough.

With this, we urge the Medicines Classifications Committee to withdraw pholcodine-containing medicines from New Zealand.

Ngā mihi,



Dr Morgan Edwards
President, New Zealand Society of Anaesthetists

1. ALPHO study: <https://www.medrxiv.org/content/10.1101/2022.12.12.22283353v1.full.pdf>
2. Relationship of perioperative anaphylaxis to neuromuscular blocking agents, obesity, and pholcodine consumption: a case-control study:
<https://www.sciencedirect.com/science/article/pii/S0007091220310072?via%3Dihub>