

8 May 2023

The Manager  
Clinical Risk Management  
Medsafe

Send via email: [medsafeadrquery@health.govt.nz](mailto:medsafeadrquery@health.govt.nz)

Dear Sir/Madam,

**Re: Review of pholcodine-containing medicines**

Thank you for the opportunity to provide feedback on the above consultation.

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing the majority of community pharmacy owners. We provide leadership on all issues affecting the sector and advocate for the business and professional interests of community pharmacy.

Our feedback on this consultation focuses on Guild members' concerns around general economic, funding and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, issues of safety, efficacy or individual patient utility.

Considering the recent evidence<sup>1,2</sup>, the recall of pholcodine by regulatory authorities in other countries<sup>3,4,5,6</sup>, and lack of suggested effective measures to minimise the risk, we recognise the benefit of pholcodine in the symptomatic treatment of a non-productive (dry) cough is moderate to low, and the risk of an anaphylactic reaction to be far greater and could be potentially life-threatening, unpredictable, and persistent for several months after exposure.

Taking into account that pholcodine is only used to treat the non-life threatening self-limiting functional symptoms of a non-productive cough with spontaneous resolution, we support the full withdrawal of all pholcodine-containing products from the New Zealand market, with the clear understanding that this would be a full Class 1 product recall at pharmacy/retail level, and that pharmacies will be able to return all unused stock (even broken original packs) for full reimbursement.

Should the Class 1 product recall be at consumer level, we request that an administration fee be paid to pharmacies per unit returned to compensate for any administration time staff would have to dedicate to this, adding to workforce pressures.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Senior Advisory Pharmacists, Martin Lowis ([martin@pgnz.org.nz](mailto:martin@pgnz.org.nz), 04 802 8218) or Cathy Martin ([cathy@pgnz.org.nz](mailto:cathy@pgnz.org.nz), 04 802 8214).

Yours sincerely,



**Nicole Rickman**  
General Manager – Membership and Professional Services

**References:**

1. Six years without pholcodine; Norwegians are significantly less IgE-sensitized and clinically more tolerant to neuromuscular blocking agents, G H de Pater et al. (2017) , <https://pubmed.ncbi.nlm.nih.gov/27859358/>
2. Prior use of pholcodine-containing cough and cold remedies and risk of perioperative anaphylactic reactions to neuromuscular blocking agents (NMBAs), WHO pharmaceuticals newsletter, (2022), <https://www.who.int/news/item/31-03-2023-pholcodine-containing-remedies-anaphylactic-reactions>.
3. Drug Safety Update: Pholcodine-containing cough and cold medicines: withdrawal from UK market as a precautionary measure. 14 March 2023. Medicines and Healthcare products Regulatory Agency, (2023), [gov.uk/drug-safety-update/pholcodine-containing-cough-and-cold-medicines-withdrawal-from-uk-market-as-a-precautionary-measure](https://www.mhra.gov.uk/drug-safety-update/pholcodine-containing-cough-and-cold-medicines-withdrawal-from-uk-market-as-a-precautionary-measure).
4. About pholcodine cough medicines cancelled by the TGA and recalled from pharmacies for safety reasons, Therapeutic Goods Administration, (2023), [tga.gov.au/safety/information-about-specific-safety-alerts-and-recalls/about-pholcodine-cough-medicines-cancelled-tga-and-recalled-pharmacies-safety-reasons](https://www.tga.gov.au/safety/information-about-specific-safety-alerts-and-recalls/about-pholcodine-cough-medicines-cancelled-tga-and-recalled-pharmacies-safety-reasons).
5. EMA recommends withdrawal of pholcodine medicines from EU market, European Medicines Agency, (2022), [ema.europa.eu/en/news/ema-recommends-withdrawal-pholcodine-medicines-eu-market](https://www.ema.europa.eu/en/news/ema-recommends-withdrawal-pholcodine-medicines-eu-market).
6. Pholcodine: Risk of Anaphylaxis to Neuromuscular Blocking Agents (NMBAs), CHOO SIM MEI, (2023), <https://www.npra.gov.my/index.php/en/component/content/article/449-english/safety-alerts-main/safety-alerts-2023/1527471-pholcodine-risk-of-anaphylaxis-to-neuromuscular-blocking-agents-nmbas.html?Itemid=1391>.