



SINGAPORE, 22 JUNE 2023

## HSA UPDATES

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**HSA UPDATES NO 2/2023**

### WITHDRAWAL OF PHOLCODINE-CONTAINING MEDICINES IN SINGAPORE

The Health Sciences Authority (HSA) would like to inform the public that all pholcodine-containing medicines will be withdrawn in Singapore. The company marketing these products, iNova Pharmaceuticals (Singapore) Pte Ltd, is cancelling the registrations of these pholcodine-containing medicines and ceasing their supply in the local market. This is a precautionary measure due to overseas findings of a rare and very small risk of severe allergic reactions (i.e., anaphylaxis) to muscle relaxants (neuromuscular blocking agents or NMBAs) used during general anaesthesia in patients who have taken pholcodine, particularly in the preceding 12 months.

2 Pholcodine is one of several medicines used to treat dry cough. In Singapore, pholcodine-containing medicines have been registered since 1993 as pharmacy-only medicines and can only be obtained from healthcare professionals, such as doctors and pharmacists. Please see **Annex A** for the list of seven pholcodine-containing medicine registered in Singapore.

3 A safety study (ALPHO study<sup>1</sup>) conducted in France found that there is a link between pholcodine and an increased risk of anaphylaxis with NMBAs used during general anaesthesia in surgeries. This safety risk is rare and assessed to be very low. To date, HSA has not received any local reports of NMBA-related anaphylactic reactions suspected to be associated with pholcodine.

4 HSA has conducted a review of the study and other available safety data and considered whether there are effective measures that can be taken to mitigate this safety risk. In consultation with medical experts from its Product Vigilance Advisory

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<sup>1</sup> [https://www.bjanaesthesia.org/article/S0007-0912\(23\)00104-6/fulltext](https://www.bjanaesthesia.org/article/S0007-0912(23)00104-6/fulltext)

Committee, HSA has concluded that the potential risks outweigh the benefits of these products, and pholcodine-containing medicines should be withdrawn from the local market as a precautionary measure.

### **Patient advisory**

5 Patients are advised on the following:

- If you are undergoing surgery involving the use of general anaesthesia and had taken any pholcodine-containing medicines, particularly in the past 12 months, inform your anaesthetist or doctor. The risk of anaphylaxis during surgeries is very rare. Anaesthetists are well trained to manage anaphylaxis and will take this into consideration during your surgery.
- Consult your doctor or pharmacist if you have any questions or concerns on the pholcodine-containing medicines you are taking or for advice on alternative treatments for dry cough.

**HEALTH SCIENCES AUTHORITY  
SINGAPORE  
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#### **▪ About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at [www.twitter.com/HSAsg](http://www.twitter.com/HSAsg).

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**Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.**

## Annex A

Table 1. List of pholcodine-containing medicines registered as pharmacy-only medicines in Singapore

<b>Brand(s) of pholcodine-containing medicine</b>
Duro-Tuss® Forte Cough Liquid 45mg/15mL Duro-Tuss® Regular Cough Liquid 15mg/15mL Duro-Tuss® Expectorant Cough Liquid Duro-Tuss® Dry Cough Lozenges (Orange flavoured) Difflam® Blackcurrant Sugar Free Cough Lozenges <i>Duro-Tuss® Decongestant Linctus [Not marketed locally]</i> <i>Duro-Tuss® Lemon Dry Cough Lozenges [Not marketed locally]</i>