Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20230989

18 MAY 2023

TO: **THE GENERAL PUBLIC, HEALTHCARE PROFESSIONALS AND MARKET AUTHORIZATION HOLDERS**

SUBJECT: **Safety Information: Pholcodine and Pholcodine-containing drug products and risk of anaphylactic reactions**

Pholcodine is an opioid medicine that is used for the treatment of non-productive (dry) cough in adults and children. It has a mild sedative effect and has a minimal to no analgesic effect. It works directly in the brain, depressing the cough reflex by reducing the nerve signals that are sent to the muscles involved in coughing. It is found in cough syrups and cough lozenges.

After the review of the European Medicines Agency on the safety of pholcodine and pholcodine-containing drug, evaluation on the evidences such as the post-marketing safety data and information submitted by healthcare professionals and the final result of the Allergy to Neuromuscular Blocking Agents and Pholcodine Exposure (ALPHO) study, data showed that use of pholcodine in the past 12 months before general anesthesia with neuromuscular blocking agents has significant risk of developing an anaphylactic reaction to these agents.

Due to this risk, some regulatory authorities have taken decisions to withdraw pholcodine and pholcodine-containing drug products from their markets.

In the Philippines, there is no registered pholcodine or pholcodine-containing drug product. However, Filipino migrant workers might have been exposed to these products previously accessible in other countries. Therefore, the FDA advises the healthcare professionals and the public on this safety risk:

Safety Information for Healthcare Professionals:

1. Assess and check the medication history of the patients who will undergo general anesthesia whether they have history of taking pholcodine or pholcodine-containing drug in the last 12 months.
2. Assess the benefit versus risks of using neuromuscular blocking agents undergoing surgery to these patients.
3. Healthcare professionals are encouraged to report any suspected serious ADRs to FDA Pharmacovigilance Section at pharmacovigilance@fda.gov.ph

Safety Information for the Patients/Consumers:

1. If you are recommended by your attending physician to undergo surgery and have taken pholcodine or pholcodine-containing drug products in the past 12 months, it is necessary to inform him/her prior to the procedure.
2. If you purchased a cough medicine (including tablets and syrups) from abroad, check the packaging or label if it contains pholcodine; talk to your attending physician or pharmacist to suggest a suitable alternative.

Information for Market Authorization Holders:

The Market Authorization Holders of neuromuscular blocking agents indicated for use during anesthesia must disseminate a Dear Healthcare communication letter informing the risk on the use of pholcodine-containing drug products linked to an increased risk of anaphylactic reaction with neuromuscular blocking agents.

For information and guidance.

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Director General

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