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FDA/HPT/VVC/SMD/VGU/23/0002

4th January 2023

Dear Healthcare Professional,

SAFETY INFORMATION ON THE RISK OF DEVELOPMENT OF ANAPHYLACTIC REACTIONS TO GENERAL ANAESTHESIA WITH NEUROMUSCULAR BLOCKING AGENTS (NMBAs) WHEN EXPOSED TO PHOLCODINE 12 MONTHS EARLIER

The Food and Drugs Authority (FDA) wishes to bring to your notice a recommendation by the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) the revocation of EU marketing authorisations for medicines containing pholcodine due to the risk of development of anaphylactic reaction to general anaesthesia with neuromuscular blocking agents (NMBAs) in patients with a 12-month prior exposure to pholcodine.

Pholcodine is a pharmacist initiated opioid cough suppressant (antitussive) that is used for the treatment of non-productive (dry) cough in children and adults, and in combination with other active substances for the treatment of symptoms of cold and flu.

The FDA would like to inform you that pholcodine-containing products have **not** been registered by the Authority and are not expected on the Ghanaian market, however, they may have been distributed illegally. This is therefore for information of healthcare professionals to assess patients scheduled for anaesthesia for the use of pholcodine-containing products in the past 12 months preceding the anaesthesia and the use of NMBAs avoided.

Further to the above, you are kindly being requested to report any pholcodine-containing product on the Ghanaian market to the FDA through the hotline 0551112224/5.

You are also requested to report adverse reactions to all products including lack of therapeutic effect and medication errors through the following:

- Download and complete the Med Safety App (Google Play Store or App Store).
- Complete and submit the report online at http://adr.fdaghana.gov.gh/
- Download and complete the Adverse Drug Reaction (ADR) Form.

Yours sincerely,

DELESE A. A. DARKO (MRS.)
CHIEF EXECUTIVE OFFICER