DR. STEPHEN OPUNI

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Dear Healthcare Professional,

SAFETY OF (DEXTRO)PROPOXYPHENE-CONTAINING PRODUCTS

The Food and Drugs Board (FDB) as part of its mandate has completed the review of the current safety information on (dextro)propoxyphene-containing products.

This review was necessitated by the withdrawal of (dextro)propoxyphene-containing products by the European Medicines Agency (EMA) in June 2009 and then by the US Food and Drugs Administration (US FDA) in November 2010. The US FDA's withdrawal was based on serious toxicity to the heart even when the product is used at normal therapeutic doses. The withdrawal by the EMA was due to increased number of reports from Forensic Centres and National Mortality Statistics from Member States indicating significant number of deaths associated with overdose.

Dextro(propoxyphene) is an opioid analgesic and it is registered by the FDB usually in combination with paracetamol for the management of mild to moderate pain. Dextro(propoxyphene)-containing products marketed in Ghana are **Co-proxamol** and **Distalgesic** tablets.

The FDB's Technical Advisory Committee on Safety has reviewed the available data to date and has concluded that since analgesics containing dextro(propoxyphene) are useful for the management of pain particularly in patients with sickle cell disease and peptic ulcer and currently there are no suitable non-opioid alternatives, complete withdrawal from the Ghanaian market will result in the unavailability of a suitable opioid analgesics for such patients.

The Committee therefore recommended that healthcare professionals do the following;

1. monitor for ECG abnormalities in patients who are prescribed these products for long periods of time.
2. monitor for deaths that may be associated with overdose and also serious toxicity to the heart when the product is used at normal therapeutic doses.

For further enquiries, complaints and reports of adverse reaction to any other medicinal product, contact the FDB through the following address.

Postal address: The Chief Executive
Food and Drugs Board
P. O. Box CT2783
Cantonments, Accra
Telephone: 0302 235100 / 0302 233200
Fax: 0302 229794
Cell Phone: 024 4310 297

Yours faithfully,

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE