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FDA/HPT/SMC/SMD/RMU/21/0002

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Audience: Anesthesiologists and Anesthetists

SUSPECTED THERAPEUTIC INEFFECTIVENESS OF BUPIVACAINE HYDROCHLORIDE INJECTION

The Food and Drugs Authority (FDA) wishes to bring to your attention that it has received a total of 19 reports of suspected therapeutic failure of Bupivacaine Hydrochloride Injection used for anesthesia in the last three years (i. e. 2017 to 2020).

Quality control laboratory analysis conducted by the FDA's Quality Control Laboratory with respect to quality and sterility of these products revealed that physicochemical and microbiological parameters were not compromised.

In view of the above, the FDA will like to bring the underlisted to the attention of anesthesiologists and anesthetists.

1. Bupivacaine hydrochloride by intrathecal anesthesia should be given only by Anesthesiologists and Anesthetists with the necessary training, knowledge and experience to avoid failure of therapy.
2. Patients requiring anesthesia should be adequately prepared as per the standard operative procedures including but not limited to preoperative assessment, appropriate hydration and pre-medication.
3. Anesthesiologists and anesthetists must ensure availability of emergency medications needed for the treatment of possible adverse effects when they occur.

Additionally, all deaths must be audited to establish the possible cause.

The FDA will like to advice healthcare professionals to report adverse reactions to all regulated products including product quality issues or medication errors by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh or call Mobile no: 0244310297 or send an email to drug.safety@fda.gov.gh or through the Med Safety App.

Yours faithfully,

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