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FDA/HPT/SMC/SMD/VGU/22/0430 19th September 2022

Dear Anaesthetics,

RISK OF SERIOUS, LIFE-THREATENING ADVERSE EVENT- BRADYCARDIA, ASSOCIATED WITH USE OF SEVOFLURANE IN DOWN'S SYNDROME PATIENTS

The Food and Drugs Authority (FDA), Ghana would like to notify you of a serious, life-threatening adverse event of bradycardia, associated with use of sevoflurane in patients with Down syndrome.

This information follows a recommendation by the Ghana Food and Drugs Authority's Technical Advisory Committee on Safety of Medicines (TAC-SM) after review of a regulatory safety action by the United States Food and Drugs Administration (US FDA). The US FDA assessed and classified bradycardia as a serious, life-threatening adverse event with reasonable causal association with use of sevoflurane in patients with Down syndrome. The safety issue is not adequately described in terms of the event or steps to decrease its likelihood or minimize its severity in the product information.

Although the FDA, Ghana has not received any report of bradycardia following use of sevoflurane in patients with Down syndrome, which could be due to the probability of few patients being operated on, a regulatory action to ensure the safety of these patients is needed due to the severity of the event.

Advice to Healthcare professionals
Healthcare professionals are advised to be vigilant when using sevoflurane and take measures to reduce the occurrence of bradycardia especially in patients with Down syndrome who are more at risk. The adverse event could also be corrected by decreasing the concentration of sevoflurane and airway manipulation.

Action by the FDA, Ghana:
The FDA, Ghana has requested marketing authorization holders of sevoflurane to update the product information with risk of bradycardia in patients with Down syndrome.

Sevoflurane is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and day surgeries.

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Table 1 provides the list of sevoflurane registered in Ghana.

Healthcare professionals are encouraged to report adverse events to sevoflurane and any other health products to FDA, Ghana by completing the adverse reaction reporting form or call **024 431 0297** or send email to drug.safety@fda.gov.gh or through the Med Safety App which is available for free on Google play store or App Store.

Yours faithfully,

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

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Table 1: List of Sevoflurane products with marketing authorization in Ghana

Product Name	Manufacturer
Sevoflurane 100% Inhalation Vapour, Liquid	Piramal Enterprises Ltd., N. H 9 Digwal Village Kohir Mandal, Kohir Cross Road, Medek Dist 502 321 Andrah Pradesh, India
Ultane Liquid for Inhalation	Aesica Queenborough Ltd, North Rd, Queenborough Me11 5el, United Kingdom
Sevofor Inhalation Solution	Atlantic Lifesciences Limited Plot No. 16/01 Larkpleku Tema-Aflao Road Tema

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