Food and Drugs Authority

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FDA/SMC/SMD/VGU/17/0_ _ _

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Dear Radiologist,

SAFETY OF INJECTABLE GADOLINIUM-BASED CONTRAST AGENTS USED IN MAGNETIC RESONANCE IMAGING (MRI) SCANS

The Food and Drugs Authority (FDA) would like to update you on the outcome of the recent review on the safety of injectable gadolinium-based contrast agents (GBCAs) by the Technical Advisory Committee on Safety of Medicines (TAC-SM).

Gadolinium is a chemical element and a component of dyes used to enhance contrast and improve radiology images. Gadolinium-based contrast agents (GBCAs) are administered by injection and used for Magnetic Resonance Imaging (MRI) scans when needed. After injection, gadolinium is eliminated through the kidneys (in urine) and for some of the agents also through the liver, but small amounts may stay in different parts of the body, including the brain.

The review by the TAC-SM is based on recent publications in the medical literature which reported that repeated use of GBCAs for MRI could lead to deposition in the brain and other tissues of patients long after the last administration.

At the moment, it is unknown whether gadolinium deposits in the brain and other tissues are harmful or can lead to adverse health effects. The FDA is reviewing the available information and the evidence in the literature and working with the Marketing Authorization Holders (MAHs) of registered products to provide appropriate information to Radiologists.

The FDA is therefore advising Radiologists and other healthcare professionals to:

- Limit the use of GBCAs to situations where the contrast agent is considered necessary.
- Use the lowest effective dose of GBCAs, and
- Assess the benefits and any potential risks to individual patients before administering repeated doses of GBCAs.

The FDA will also like to inform Radiologists that the available scientific evidence suggests that gadolinium accumulation in the brain is higher with the use of linear agents than with the use of macrocyclic agents, but it has occurred with both types.

GBCAs registered by the FDA for use in Ghana are:

Brand Name	Generic	Type of GBCA	Marketing Authorization Holder
Omniscan	Gadodiamide	Linear agent	GE Healthcare
Magnevist	Gadopentetate Dimeglumine	Linear agent	Bayer

Although the Food and Drugs Authority has not received any adverse event of gadolinium deposition in the brain and other tissues, Radiologists and healthcare professionals are encouraged to report adverse events to GBCAs and any other medications to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call **024 431 0297** or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

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