Food and Drugs Authority

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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.