EMA reviewing gadolinium contrast agents used in MRI scans
Review to consider evidence on gadolinium accumulation in brain tissue

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Information on gadolinium contrast agents

- Gadolinium contrast agents contain gadolinium, which is used as a 'contrast enhancer' to help make body tissues more visible on the scan.
- This review covers agents containing the following active substances: gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid.
- Most gadolinium-containing contrast agents have been authorised nationally in the European Union (EU). OptiMARK (gadoversetamide) is currently the only centrally authorised gadolinium contrast agent in the EU.

In Malta the following products are authorised through various licensing procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Gadobutrol	Gadovist	Solution for injection	POM	AA513/01201-01202	Bayer PLC
Gadopentate Dimeglumine	Magnevist	Solution for injection	POM	MA185/01001	Bayer PLC
Gadodiamide	Omniscan	Solution for injection	POM	MA023/00101	GE Healthcare AS
Gadoversetamide	OptiMARK	Solution for injection	POM	EU/1/07/398/001-014	Mallinckrodt Deutschland GmbH
Gadoxetic Acid, Disodium	Primovist	Solution for injection	POM	MA513/03501	Bayer PLC
Gadoxetic Acid, Disodium	Primovist	Solution for injection	POM	PI770/07601A	JV Healthcare Limited

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Information about the review to consider evidence on gadolinium accumulation in brain tissue

The European Medicines Agency (EMA) has started a review of the risk of gadolinium deposition in brain tissue following the use of gadolinium contrast agents in patients having magnetic resonance imaging (MRI) scans.

- Gadolinium contrast agents are diagnostic products that may be given to patients before or during MRI scans to help doctors obtain better images of organs and tissues. After administration, gadolinium agents are mostly eliminated via the kidneys but studies indicate that deposits can build up in some body tissues, including in the liver, kidney, muscle, skin and bone.
- Recently, a number of publications have reported that gadolinium contrast agents also accumulate in brain tissue[1-7]. In January 2016, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) reviewed these publications.
- Although no adverse effects relating to gadolinium brain deposition have been reported to date, the PRAC will carry out an in-depth review of the risk of brain deposits and of the overall safety of these products and issue recommendations.

The PRAC's recommendations will be sent to Committee for Medicinal Products for Human Use (CHMP), which will issue the Agency's final opinion in due course. For more information on review of gadolinium contrast agents please refer to the European Medicines Agency's press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on gadolinium contrast agents. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending to **http://www.medicinesauthority.gov.mt/adrportal** or online at http://www.medicinesauthority.gov.mt/adrportal or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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