IMPORTANT MEDICINE SAFETY INFORMATION

18 June 2018

Dear Healthcare Professional

RE Gadolinium-based Contrast Agents (GBCAs): Gadolinium deposition in the brain

The following pharmaceutical companies: AXIM Pharmaceuticals (Pty) Ltd, Guerbet South Africa (Pty) Ltd and GE Healthcare SA in collaboration with South African Health Products Regulatory Authority (SAHPRA) would like to inform you of the safety information regarding the risk of gadolinium brain deposition following the use of GBCA's.

This safety update is based on Committee for Medicinal Products for Human Use (CHMP) opinion endorsed by the European Commission's (EC) decision, to suspend the intravenous use of general purpose linear GBCAs in all European Union (EU)/European Economic Area (EEA) Member States. The EC decision has provided EU/EEA Member States, the option to defer the suspension, for up to 12 months after the date of this Decision (i.e. November 2018).

Gadolinium retention in the brain has been reported with all types of GBCAs, both linear and macrocyclic. There is currently no confirmed evidence that gadolinium deposition in the brain has caused any harm to patients.

In Europe, the final decision of the European Commission was to suspend the approvals of intravenous linear agents in the EU with the exception of gadoxetic acid and gadobenic acid which remain available for liver scans only and gadopentetic acid which will continue to be available solely for intra-articular use.

AXIM Pharmaceuticals, Guerbet South Africa and GE Healthcare SA are in the process of updating Professional Information and Patient Information Leaflets to reflect the above mentioned information.

Healthcare professionals are advised to limit gadolinium-based contrast agent use to circumstances where the extra information provided by the contrast agent is necessary, and in those circumstances to use the lowest effective dose and carefully consider the choice of agent (linear or macrocyclic). It is also recommended that healthcare professionals avoid repetitive scans using these contrast agents unless deemed clinically necessary.

Healthcare professionals should report any adverse drug reactions associated with the use of GBCAs to:

SAHPRA Pretoria Office:

Email - adr@health.gov .za

Telephone - 012 395 9133

Fax - 086 620 7253

OR

National Adverse Event Monitoring Centre (NADEMC):

Telephone - 021 447 1618

Fax - 021 448 6181

OR

AXIM Pharmaceuticals (Pty) Ltd:

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