

# MEDICINES CONTROL COUNCIL



## **MEDICINE SAFETY ALERT: ROTARIX VACCINE FOR ORAL ADMINISTRATION: REPORTS OF THE INCORRECT ROUTE OF ADMINISTRATION**

***The Medicines Control Council (MCC) alerts all health care professionals to the correct route of administration of Rotarix vaccine.***

The Medicines Control Centre (MCC) wishes to draw the attention of all health care professionals to the correct route of administration of Rotarix Vaccine.

Rotarix Vaccine is indicated for the prevention of gastroenteritis caused by Rotavirus, G1 and non-G1 serotypes (such as G2, G3, G4 and G9) in infants from the age of 6 weeks. This vaccine is given **orally**, unlike many other vaccines.

Cases of the incorrect route of administration for Rotarix vaccine have been reported locally and internationally. The NADEMC has received 5 reports, while a Dear Health Care Professional letter distributed in the UK in October 2006 made reference to 20 reports worldwide involving the reconstituted vaccine administered intramuscularly instead of orally.

The package insert for Rotarix oral vaccine warns that the vaccine should under no circumstances be injected, and states that Rotarix is for oral use only.

Prescribers and Primary Health Care Professionals are advised to follow the dosage instructions and route of administration as indicated in the package insert for the Rotarix vaccine.

Health care professionals are encouraged to report any adverse reactions associated with the use of medicines to the MCC's National Adverse Drug Event Monitoring Centre (NADEMC) by telephone (021 447 1618, fax 021 448 6181 or mail to : Department Of Health, Registrar of Medicines, Private Bag X828, Pretoria , 0001).

*Reference: B10.8 MCC26*