Malta, 25 March 2010
Circular No. P04/2010

Dear Healthcare Professional,

European Medicines Agency sees no safety concerns with the Rotarix oral vaccine

Information from the press release issued by the European Medicines Agency is being reproduced below;

'The European Medicines Agency has concluded that the unexpected presence of DNA of a non-disease causing viral strain in batches of the oral vaccine Rotarix does not present a risk to public health. At an extraordinary meeting held on 25 March 2010, the Committee for Medicinal Products for Human Use (CHMP) endorsed the recommendations from its Vaccines Working Party and agreed that there was no need to restrict the use of Rotarix.

Rotarix is a vaccine given by mouth to children of 6 weeks and older, to protect against gastroenteritis (diarrhoea and vomiting) due to rotavirus infection.

The DNA found in the vaccine matches that of porcine circovirus type 1 (PCV1). This virus is commonly found in certain meat and other food products, and is not known to cause disease in either animals or humans. The DNA has not been found in other live attenuated vaccines from the same manufacturer, GSK Biologicals.

However, viral DNA should not be present in the Rotarix vaccine and its source is unclear. The Committee has therefore requested that the manufacturer identifies the root cause of the finding and introduces measures to manufacture the vaccine free of PCV1 DNA.

The CHMP will be reviewing all new data on an ongoing basis. The Committee will consider the need for further recommendations in its meetings in April and May 2010, as further data emerges.'

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal.

Post-licensing Directorate
Medicines Authority

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