



**- Please bring to the attention of all doctors -**

Date: 26 March 2010

Contact telephone number: **8226-7177 (24 hours/7 days)**

## ROTAVIRUS VACCINE INFORMATION

On 24<sup>th</sup> March the Therapeutic Goods Administration (TGA) released a statement with information on a quality issue relating to the manufacturing of the GlaxoSmithKline (GSK) Oral Rotavirus Vaccine - Rotarix®. DNA fragments of a virus identified as porcine circovirus type 1 (PCV1) had been found in batches of the product. PCV1 is common in pigs but does not cause illness in pigs or any other animals, nor has it been shown to cause illness or replicate in humans.

In Australia two oral Rotavirus vaccines (Rotarix® and RotaTeq®) are approved for use. SA Health purchases and distributes RotaTeq® only.

All providers who use rotavirus vaccine distributed by SA Health will be using RotaTeq®. There are no concerns with this product.

The Northern Territory distributes vaccine on behalf of South Australia to Nganampa Health Service in the APY Lands. NT Health uses Rotarix®.

The TGA is working closely with other regulatory agencies overseas and the company, GSK, to obtain information and expert advice. In addition, the TGA is convening an expert panel to provide further advice on the matter. In the interim, the TGA has advised that the Rotarix® vaccine is safe and effective and vaccination programs should continue to use Rotarix®.

Further information and a Q and A sheet can be found at;

[www.tga.gov.au/alerts/medicines/rotarix.htm](http://www.tga.gov.au/alerts/medicines/rotarix.htm)

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*Information contained within this advice should be treated as confidential and is for the intended recipient only.*