



Australian Government
Department of Health and Ageing

Statement for Immunisation Providers on Rotarix[®] (Rotavirus Vaccine)

29 March 2010

The Department of Health and Ageing has been advised by the Therapeutic Goods Administration (TGA) that the rotavirus vaccine, Rotarix[®], should continue to be used in the National Immunisation Program (NIP). The vaccine is used in New South Wales (NSW), Australian Capital Territory (ACT), Northern Territory (NT) and Tasmania (TAS).

Rotavirus vaccine is included under the NIP for protection against rotavirus gastroenteritis, an illness which can be severe and which, prior to the introduction of the vaccine, resulted in an estimated 10,000 hospitalisations per year in children under the age of 5 years in Australia. Vaccination with Rotarix[®] should be given as scheduled for babies at 2 and 4 months of age.

On 17 March 2010 GlaxoSmithKline (GSK) notified the TGA that DNA fragments of a virus identified as porcine circovirus type 1 (PCV1), had been found in batches of the product. Follow-up with newly developed tests has confirmed the presence of DNA from PCV1 in finished vaccine lots tested, as well as in intermediates in the production process, and in the working cell bank and viral "seed" from which the vaccine was derived. DNA from PCV-1 has been present since the initial stages of the development of Rotatrix.

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. TGA considers that the safety of the Rotarix[®] vaccine has not been compromised by the detection of these fragments.

TGA has reviewed the current evidence and does not consider there is a threat to public health. The risk of any illness from ingesting such material is remote.

Clinical trials data and extensive experience to date have demonstrated that Rotarix[®] is effective in preventing infection with rotavirus and is well tolerated in babies.

More information is available at: <http://www.tga.gov.au/alerts/medicines/rotarix.htm>.