



**Australian Government**  
**Department of Health and Ageing**

CHIEF MEDICAL OFFICER

Dear Colleague

**Intussusception and rotavirus vaccine**

I am writing to advise you of new evidence suggesting a small increased risk of intussusception in infants following rotavirus vaccination. I recommend that you continue to vaccinate young infants against rotavirus but that you inform parents and carers of the rare risk of intussusception and how to be alert for the signs and symptoms of the condition. The risks from rotavirus infection and benefits of vaccination should also be discussed.

Intussusception is a rare condition, with an annual incidence under 12 months of age in Australia of 80 per 100,000, which represents approximately 200 cases per year. The increased risk of intussusception appears to occur mainly in the first 1-7 days following the first dose of vaccine and represents approximately 2 additional cases of intussusception among every 100,000 infants vaccinated, or 6 additional cases per year in infants in Australia. It remains uncertain whether increased incidence in the first week after vaccination represents an overall increase in the incidence of intussusception. Studies are ongoing to determine if there is an increased risk after other doses or for up to three weeks after vaccination.

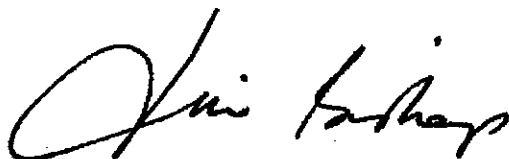
The increase in risk, which was not apparent in the large clinical studies carried out prior to registration of the vaccine, has been found through specific post-marketing surveillance studies undertaken in Australia and overseas.

The very low risk of intussusception must be balanced against the benefits of rotavirus vaccination. Prior to the introduction of rotavirus vaccine, there were an estimated 10,000 hospitalisations annually in children under 5 years of age due to rotavirus gastroenteritis in Australia. Since the introduction of Rotarix® and RotaTeq® to the National Immunisation Program in 2007, this has been reduced by over 70%.

Based on the well-established benefits of rotavirus vaccination and the rare occurrence of intussusception, both rotavirus vaccines continue to be registered by the Therapeutic Goods Administration (TGA) for the prevention of rotavirus gastroenteritis and the Australian Technical Advisory Group on Immunisation (ATAGI) recommends the continued use of rotavirus vaccine for infants under the National Immunisation Program. The continued use is also supported by the World Health Organization.

The enclosed *Summary Information for Immunisation Providers* provides further information that will assist you in your discussions with parents. A parent *Fact Sheet* and the more detailed booklet *Information for Immunisation Providers* are both available on the **Immunise Australia** website at [www.immunise.health.gov.au](http://www.immunise.health.gov.au) Information about the studies that have shown this increased risk is published on the Therapeutic Goods Administration (TGA) website at [www.tga.gov.au/safety/alerts-medicine-rotavirus-110225.htm](http://www.tga.gov.au/safety/alerts-medicine-rotavirus-110225.htm). Information is also available through the **Immunise Australia Call Centre** on 1800 671 811.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Jim Bishop', written in a cursive style.

**Professor Jim Bishop AO**  
MD MMed MBBS FRACP FRCPA

25 February 2011