監測及流行病學處

衞生防護中心
Centre for Health Protection
保障市民健康
Protecting Hong Kong's health

Surveillance
And
Epidemiology
Branch

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Dear Doctor,

CDC Releases Safety Data on Rotavirus Vaccine Reported Intussusception Cases Fall Within Expected Range

Further to the letter dated 15 February, I would like to provide you an update of the situation. A press release was issued by the US Centers for Disease Control and Prevention (CDC) on 15 March, 2007 (US time) regarding RotaTeq and intussusception, which can be accessed at http://www.cdc.gov/od/oc/media/pressrel/2007/r070315a.htm, part of it was excerpted as follows:

> *"The Centers for Disease Control and Prevention (CDC) released today new safety data on a recently licensed rotavirus vaccine given to infants that indicate the vaccine does not pose an elevated risk for intussusception, the most common cause of bowel obstruction in infants."*
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> *"The vaccine, sold by Merck and Company under the brand name RotaTeq, was licensed by the U.S. Food and Drug Administration (FDA) in February 2006. The Advisory Committee on Immunization Practices (ACIP) recommends RotaTeq for routine vaccination of U.S. infants to protect against rotavirus, which causes severe diarrhea, vomiting, fever and dehydration (gastroenteritis) in children."*
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> *"Last month, FDA notified healthcare providers and consumers that it had received reports of intussusception following RotaTeq vaccination. Since then, FDA, ACIP and CDC have concluded that the number of intussusception reports after administration of RotaTeq has not exceeded the number expected to occur without vaccination and that the vaccine does not appear to be associated with intussusception."*

"Monitoring the safety of a new vaccine is very important," said Anne Schuchat, M.D., director of CDC's National Center for Immunization and Respiratory Diseases. "The data we have reviewed are reassuring, and we continue to recommend the RotaTeq vaccine. However, we will continue to carefully monitor reports of possible adverse effects associated with the vaccine and will take appropriate action if there proves to be a problem in the future."

In Hong Kong, RotaTeq is a prescription drug registered in December 2006. The Department of Health (DH) has not received any reports of adverse effects related to the vaccine in Hong Kong.

Doctors who suspect a child developing signs and symptoms of intussusception following RotaTeq administration are encouraged to report it to the DH by calling DH's adverse drug reactions hotline 2319 8482 during office hours.

Thank you very much for your kind attention.

Yours faithfully,

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