衞生署
藥物註冊組
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28th February 2011

Dear Healthcare Professionals,

Updated Safety Information on Rotavirus Vaccination and Risk of Intussusception

Your attention is drawn to the report of the Austrialian Therapeutic Goods Administration (TGA) on an investigation of a possible association between the use of the rotavirus vaccines Rotarix® (GSK) and RotaTeq® (Merck/CSL) and the occurrence of a rare form of bowel obstruction known as intussusception (IS). Intussusception is a condition caused by the telescoping of one segment of the bowel into another.

This interim analysis provides evidence that both registered rotavirus vaccines are likely to be associated with an increase in risk of IS in the 7 days following the first dose of both Rotarix and RotaTeq. Despite the identification of a small increase in risk of IS following the first dose of rotavirus vaccination, the TGA considers that the overall risk benefit balance of both vaccines remains positive. The Product Information documents for both vaccines will be amended to reflect these findings. It is also important to note that both the World Health Organization (WHO) and the Australian Technical Advisory Group on Immunisation (ATAGI) have recommended the continued use of rotavirus vaccine for infants.
For detail, please refer to the TGA's website : -
http://www.tga.gov.au/safety/alerts-medicine-rotavirus-110225.htm

In Hong Kong, Rotarix Vaccine Oral Suspension (HK-54546) is registered by Glaxosmithkline Limited, and RotaTeq Oral Vaccine (HK-55037) is registered by Merck Sharp & Dohme (Asia) Limited. Both Rotarix and RotaTeq are prescription drugs. Both companies will follow up with their head offices regarding the above safety information. Any further updates made by the TGA and other regulatory authorities will be kept in view.

Please report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147-0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Pharmaceutical Service under "Reporting an Adverse Drug Reaction".

Yours faithfully,

(Ms. Pamela LI)
for Chief Pharmacist