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Dear Doctor,

**Labelling Revision for RotaTeq**

We would like to inform you that the US Food and Drug Administration (FDA) approved a revised label for RotaTeq, a rotavirus vaccine manufactured by Merck and Co., Inc., to include information on reports of Kawasaki disease occurring before and after the vaccine's licensure. Please refer to <http://www.fda.gov/cber/label/rotateqLBinfo.htm> for details.

The *Adverse Reactions* section of the label was updated to include six cases (five cases among infants who received RotaTeq and one received placebo) of Kawasaki disease that were observed during the Phase 3 clinical trial. Additionally the *Post-marketing* section of the label has been revised to reflect three reports of Kawasaki disease to the Vaccine Adverse Event Reporting System since licensure on February 3, 2006.

According to FDA, there was not a known cause and effect relationship between receiving RotaTeq, or any vaccine and the occurrence of Kawasaki disease. The cases reported to date are not more frequent than what could be expected to occur by coincidence. Regarding the use of RotaTeq, FDA has not made any changes to its indications, warnings or precautions, and the US Centers for Disease Control and Prevention (CDC) has not made any changes in its recommendations. Both organizations stated that healthcare providers and parents should remain confident in using RotaTeq in infants. FDA is working with Merck and the CDC to further study the occurrence of Kawasaki disease after vaccination.

Kawasaki disease is a serious, but uncommon illness in children that is poorly understood and the cause has not been determined. It is characterized by high fever and inflammation of the blood vessels and affects the lymph nodes, skin, mouth and heart. It mainly affects children younger than 5 years of age.

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

Doctors who suspect a child developing Kawasaki disease or other severe adverse events following administration of RotaTeq or other vaccines are encouraged to report it to the DH by calling DH's adverse drug reactions hotline 2319 8482 during office hours.

Yours sincerely,



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