Press Statement

PRESENCE OF DNA FRAGMENTS FROM PORCINE CIRCOVIRUS TYPE 1 (PCV-1) IN HUMAN ROTAVIRUS (HRV) VACCINE – ROTARIX™

GlaxoSmithKline (GSK) Malaysia reported the presence of DNA fragments from Porcine Circovirus Type 1 (PCV-1) in its Human Rotavirus (HRV) vaccine, Rotarix™. This was based on findings from an independent academic research team, led by Prof. Eric Delwart from the Department of Laboratory Medicine, UCSF, USA. The presence of PCV-1 DNA fragments was then confirmed by additional tests conducted by GSK. PCV-1 is not known to replicate and cause illness in either humans or animals. This virus is not originated from pigs and is commonly found in meat products. Although DNA fragments from PCV-1 have been detected in Rotarix™, it is not yet known whether this indicates that intact virus is present.

GSK has reviewed the manufacturing process for the vaccine and re-assessed all the adverse reaction reports received through clinical research and surveillance, and it was found that no adverse event was identified to be related to the presence of components of the extraneous virus in the vaccine.

European Medicine Agency (EMA) and World Health Organization (WHO) considered the benefits of vaccination against rotavirus infection are substantial and far outweigh any theoretical risk of harm from the vaccine. Therefore, these agencies concluded that no action was necessary at this point. The United States Food and Drug Administration (FDA) recommend temporary suspension of the use of Rotarix™ while the agency learns more about the situation. There is no evidence at this time that this finding poses a safety risk.

The Drug Control Authority (DCA) has registered Rotarix™ Oral Vaccine (MAL20091875A) and Rotarix™ Rotavirus Vaccine (MAL20061522A). These products are indicated to protect against gastroenteritis due to rotavirus infection, which can cause severe diarrhoea and dehydration. Rotavirus infection is estimated to be responsible for approximately 572,000 deaths each year in children below 5 years around the world.

The Malaysian Adverse Drug Reaction Monitoring Program has received 14 reports related to the use of Rotarix™. The adverse reactions involved include *diarrhea* (6), *gastroenteritis* (5), *intussusceptions* (1), *vomiting* (2), *fever* (2) and *appetite loss* (1)

As further assessments are ongoing to obtain more information about the PCV-1 components in Rotarix™, no regulatory action is warranted at this moment. The DCA will continue to monitor and review any new safety information available regarding these products for further regulatory action.

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As DCA Chairman
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