FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE

19 MAY 2010

HSA UPDATES ON ITS REVIEW OF THE PRESENCE OF PORCINE CIRCOVIRUS (PCV) IN ROTAVIRUS VACCINES

The Health Sciences Authority (HSA), in consultation with the Ministry of Health (MOH) and its Expert Committee for Immunisation (ECI) would like to update on its review of the presence of porcine circovirus (PCV) in rotavirus vaccines and its recommendations on the use of rotavirus vaccines in Singapore.

Background Information

2 Minute fragments of a virus particle of the porcine circovirus-1 (PCV-1) has been found in the rotavirus vaccines: Rotarix™ (GlaxoSmithKline,GSK) and RotaTeq™ (Merck Sharp & Dohme, MSD). Additionally, minute quantities of porcine circovirus-2 (PCV-2) was detected in RotaTeq™. Rotarix™ and RotaTeq™ have been licensed in Singapore since 2005 and 2007 respectively for the vaccination of infants against gastro-enteritis (a condition that causes irritation and inflammation of the stomach and intestines) due to rotavirus infection. Rotavirus vaccination is an optional vaccination not included in the Childhood Immunisation Programme in Singapore.

3 Both Rotarix™ and RotaTeq™ vaccines have been studied extensively in clinical trials involving tens of thousands of patients and used in millions of patients globally in clinical practice. There have been no significant safety issues observed with these vaccines to date.

Rotarix™

4 Based on the current available information from over 20 clinical studies and local and international post-marketing surveillance, there is no evidence at this time that suggest that this finding poses a safety risk. Ongoing investigations by the company showed that the PCV-1 fragments found in the final vaccine is unlikely to cause infection in human cells when used at recommended doses. Current available data also suggests that there were no cases of PCV-1 infection in infants who had received Rotarix™ in clinical trials.

RotaTeq™

5 While initial tests for PCV-1 did not show the presence of these fragments in RotaTeq™, additional testing conducted by the company detected the presence of PCV-1 and PCV-2 fragments in the vaccine. The levels of the PCV fragments in Rotateq™ appear to be many times lower than the levels detected in Rotarix™.

Background on PCV-1 and PCV-2

6 Porcine circovirus 1 (PCV-1) is a virus known only to infect birds and pigs, hence the term “porcine”. This does not mean that the rotavirus vaccines are of pig origin. PCV-1 is widespread in pigs and the virus has not been linked to any animal disease. PCV-2 may infect piglets, resulting in an inability to gain weight. There is no documentation so far that PCV-1 and 2 can infect humans and is not known to cause illness in humans.

HSA’s Actions and Assessment

7 HSA has convened a meeting with the Ministry of Health (MOH) and its Expert Committee on Immunisation (ECI) on 13 May 2010 to seek expert opinions on this issue. The meeting reviewed the scientific and clinical evidence currently available and assessed that the benefits of rotavirus vaccination in Singapore outweighs the theoretical risk posed by the PCV contaminants in the vaccine. HSA and MOH’s ECI recommends that both Rotarix™ and RotaTeq™ can continue to be used for the local infant population.

8 To date, HSA Vigilance Branch has not received any local adverse event reports associated with rotavirus vaccines which appear to be related to this issue but will continue to monitor the situation and provide updates as appropriate.

Public Advisory

9 Infants who are currently on rotavirus vaccination schedule (either Rotarix™ or RotaTeq™) should complete the course of vaccination as advised by their doctors. Parents of infants who have concerns about the rotavirus vaccination or who are considering rotavirus vaccination for their infants are advised seek medical advice and obtain more information from their doctors prior to the vaccination.

HEALTH SCIENCES AUTHORITY
19 MAY 2010

- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

- **About HSA's Health Products Regulation Group**

The Health Products Regulation Group (HPRG) of HSA contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework. It ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.