DRUG SAFETY INFORMATION No.31

Health Products Regulation Group
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Dear Healthcare Professional

UPDATE ON THE RECENT FINDING OF PORCINE CIRCOVIRUS-1 (PCV-1) DNA FRAGMENT IN ROTAVIRUS VACCINE (ROTARIX®)

The Health Sciences Authority (HSA) would like to update healthcare professionals on the recent finding by researchers from the University of California, San Francisco regarding the presence of DNA fragment of porcine circovirus (PCV-1) found in the rotavirus vaccine, Rotarix® (GSK) and HSA's interim position on this matter. While HSA is reviewing the significance of this new finding, healthcare professionals are advised to consider deferring immunisation with Rotarix® or consider an alternative vaccine till more information becomes available.

2 Rotarix® is one of the two rotavirus vaccines licensed in Singapore for the vaccination of infants 6 weeks and older against gastro-enteritis due to rotavirus infection since October 2005. The other locally licensed rotavirus vaccine is RotaTeq®, which has not been found to carry the PCV-1 DNA fragment at this point of time.

Background

3 An independent research team from the University of California, San Francisco has identified a DNA fragment of PCV-1 in the rotavirus vaccine, Rotarix®. Further investigations conducted by GSK confirmed presence of PCV-1 DNA in those batches and in human rotavirus vaccine starting materials. The PCV-1 DNA fragment has been incorporated into the vaccine during the manufacturing process. The viral component has been present since the initial stages of the vaccine's development in the cell bank and rotavirus seeds used as base production material. This same manufacturing process has been used from the time the vaccine was studied in clinical trials up till today to produce commercial lots for sale.

More information on PCV-1

4 PCV-1 is known only to infect birds and pigs. PCV-1 is widespread in pigs and the virus has not been linked to any animal disease. PCV-1 does not multiply in humans and is not known to cause illness in humans. It is found in everyday meat products and is frequently eaten with no resulting disease or illness. There have been no reports of human illness from the use of Rotarix® known to be related to the presence of the PCV-1 DNA fragment.

Overseas regulatory decisions and actions

a) US Food and Drug Administration (FDA)

5 Currently, FDA is obtaining additional information about the presence and origins of DNA from PCV1 in Rotarix® including making a determination of whether intact virus (as opposed to DNA fragments) is present. The FDA will convene an advisory committee within the next 6 weeks to review the available data and make recommendations on their licensed rotavirus

vaccines, Rotarix® and Rotateq®. FDA has anticipated that the agency will make further recommendations on the use of rotavirus vaccines in the United States following the meeting. During this interim period**,** the agency recommends that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix®.

b) European Medicines Agency (EMA)

6 An initial review by the Agency's Committee for Medicinal Products for Human Use (CHMP) considered the same research findings and concluded that no action was necessary at this point. The Agency is working closely on this matter with its international counterparts. A meeting of the CHMP Vaccine Working Party has been called for on 23-24 March 2010 with the participation of WHO, and international regulators and the next steps will be considered at an extraordinary meeting of the CHMP to be held on 25 March 2010.

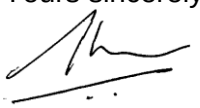
HSA's assessment and recommendations

7 Based on the available information from clinical trials and the post-marketing surveillance data representing more than 69 million doses of Rotarix® sold globally, there is no evidence at this time that suggest that this finding poses a safety risk. The Vigilance Branch has also not received any local adverse event reports associated with rotavirus vaccines which appear to be related to this issue.

8 As the significance of this PCV-1 DNA fragment is still not completely known and investigations are ongoing, healthcare professionals may wish to temporarily defer immunisation with Rotarix® or consider an alternative vaccine till more information becomes available. HSA will continue to evaluate new data as soon as it becomes available and keep healthcare professionals updated on this issue.

9 Please contact Dr Yvonne Koh at Tel: 6866 3550 or email: yvonne_koh@hsa.gov.sg should you have any queries on the above information.

Yours sincerely



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