STATEMENT

Rotavirus Vaccine Contamination with PCV1

STATEMENT OF IAP COMMITTEE ON IMMUNIZATION

Following the reports of temporary suspension ordered by the US FDA on the use of Rotarix (rotavirus vaccine by GSK) on the issue of contamination of the vaccine with porcine circovirus type-1 (PCV-1), the IAP COI has gone through the exact chronology of events (***Annexure* 1**).

After having thoroughly reviewed the reports of various agencies and institutions, and in view of the recent final statement issued by the Strategic Advisory Group of Experts (SAGE) on Immunization, WHO (see ***Annexure* 2**), the IAP COI makes no amendments to its existing recommendations, on the use of Rotavirus vaccine, released and published in 2008(1). It believes that use of currently available rotavirus vaccine in the country, poses no immediate health threats to the vaccinees.

Vijay N Yewale and Panna Choudhury,
IAP Committee on Immunization,
vnyewale@gmail.com

Annexure 1

CHRONOLOGY OF EVENTS

- The presence of DNA material from PCV-1 in Rotarix (Rotavirus vaccine) was first detected following work done by a research team in the US using a novel technique for looking for viruses and then shared with GSK.
- After being notified, GSK conducted additional tests which confirmed the findings.
- GSK confirmed that the presence of material in the finished Rotarix vaccine as well as in the cell bank and seed from which the vaccine is derived.
- GSK notified regulatory authorities worldwide of the presence of DNA material from PCV-1 in Rotarix (Rotavirus vaccine) including Indian Drug Authorities (Office of DCGI).
- Statements were issued on March 22, 2010 by FDA, EMA, WHO along with GSK, explaining the situation(2-5).
- GSK issued a press release at a global level confirming that it has notified regulatory authorities worldwide of the presence of material from PCV-1 in Rotarix(5).
- This was followed by TGA statement on 24 March, 2010 in support of continuing use of Rotarix(6) .
- The European Medicines Agency (EMA) issued a press release on 26th March 2010 and concluded that the unexpected presence of DNA of a non-disease causing viral strain in batches of the oral vaccine Rotarix does not present a risk to public health. At an extraordinary meeting held on 25 March 2010, the Committee for Medicinal Products for Human Use (CHMP) endorsed the recommendations from its Vaccines Working Party and agreed that there was no need to restrict the use of Rotarix(7).
- WHO Global Advisory Committee on Vaccine Safety (GACVS) on Rotarix was released on 26th Mar 2010. It states that "Given the extensive clinical data supporting the safety of Rotarix and the benefits of rotavirus vaccination for children, GACVS considers that the benefits of vaccination far outweigh any currently known risk associated with use of Rotarix"(8).
- GSK issued a second press release on 26March 2010 confirming the position statements of EMA and CHMP which is in line with previous

communications by WHO, FDA, other national regulatory agencies as well as GSK that the presence of the material does not present a safety risk(9).

- PCV-1 does not multiply in humans and is not known to cause any illness in humans(10,11). It is found in everyday meat products and is eaten with no resulting disease.

Annexure 2

STATEMENT ISSUED BY THE STRATEGIC ADVISORY GROUP OF EXPERTS (SAGE) ON IMMUNIZATION, WHO

- April 2010 meeting of the Strategic Advisory Group of Experts (SAGE) - SAGE noted that PCV1 is not known to cause disease in animals or humans. PCV1 DNA is often found in food products and has been detected in human stool specimens from healthy children who have not received Rotarix vaccine. The safety of Rotarix is supported by both large prelicensure clinical trials (more than 50,000 subjects) and an extensive postlicensure safety experience (over 60 million doses of vaccine administered). SAGE noted the conclusions of GACVS indicating that the extensive clinical data support the safety of Rotarix and that GACVS was of the view that the benefits of rotavirus vaccination for children far outweigh any known risk associated with use of Rotarix. Rotavirus gastroenteritis is the most common cause of severe diarrheal disease in young children throughout the world and rotavirus immunization is recommended by WHO(12,13). Given the absence of any known risk, SAGE strongly recommends the continued use of Rotarix for immunization programs, in particular in those parts of the world with elevated under-5 mortality associated with rotaviruses. SAGE requested to be regularly updated by GACVS as new information becomes available(14).

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