

22 March 2010

Rotavirus vaccination - WHO does not recommend any change to use of Rotarix vaccine

Following announcements today by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) regarding use of the rotavirus vaccine, Rotarix, the World Health Organization (WHO) encourages all countries using the vaccine to carefully consider the significant benefits of continued use of the vaccine in any decisions about further use.

The FDA and EMA statements follow the recent report to the vaccine manufacturer that DNA sequences originating from porcine circovirus 1 (PCV1) had been detected in two batches of the vaccine during a study undertaken in the United States of America (USA).

WHO concurs with the views of the FDA and EMA that the findings do not present a threat to public health. Moreover, rotaviruses are the most common cause of severe diarrhoeal disease in young children throughout the world, with an estimated 527 000 deaths among children under five years old, most of whom live in low-income countries. Therefore, WHO does not recommend any change to use of the vaccine. The vaccine is prequalified by WHO, and the prequalification status remains unchanged.

WHO will continue to work closely with the FDA, EMA and other regulatory agencies to evaluate further information that the manufacturer will be providing as a matter of urgency.

- [WHO position paper on rotavirus vaccines \[pdf 764kb\]](#)
- [United States Food and Drug Administration statement](#)
- [European Medicines Agency statement](#)

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