



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency sees no safety concerns with the Rotarix oral vaccine

The European Medicines Agency has 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.

Rotarix is a vaccine given by mouth to children of 6 weeks and older, to protect against gastroenteritis (diarrhoea and vomiting) due to rotavirus infection.

The DNA found in the vaccine matches that of porcine circovirus type 1 (PCV1). This virus is commonly found in certain meat and other food products, and is not known to cause disease in either animals or humans. The DNA has not been found in other live attenuated vaccines from the same manufacturer, GSK Biologicals.

However, viral DNA should not be present in the Rotarix vaccine and its source is unclear. The Committee has therefore requested that the manufacturer identifies the root cause of the finding and introduces measures to manufacture the vaccine free of PCV1 DNA.

The CHMP will be reviewing all new data on an ongoing basis. The Committee will consider the need for further recommendations in its meetings in April and May 2010, as further data emerges.

Notes

1. More information on Rotarix is available in the European public assessment report (EPAR) at <http://www.ema.europa.eu/humandocs/Humans/EPAR/rotarix/rotarix.htm>.
2. See also the European Medicines Agency statement on new information on Rotarix oral vaccine, dated 22 March 2010: <http://www.ema.europa.eu/humandocs/PDFs/EPAR/rotarix/18935010en.pdf>.



3. Rotarix contains a live attenuated ('weakened') virus. It is prepared from live human rotavirus strains that are manipulated to make them unable to cause the disease, while keeping their ability to trigger an immune response.
4. Rotarix was approved in the European Union in February 2006. It is not usually part of Member States' childhood vaccination schedules, but is available in all Member States. The vaccine is widely used outside of the European Union and is part of the World Health Organization (WHO) prequalification programme for vaccines. Some 51,000 children received the vaccine in clinical trials (out of a total of 91,000 children) and about 68 million doses have been distributed worldwide to date.
5. The WHO estimates that rotaviruses are responsible for approximately 527,000 deaths each year, with more than 85% of these deaths occurring in low-income countries in Africa and Asia. See here: http://www.who.int/immunization/newsroom/news_rotavirus_vaccine_use/en/.
6. The review is being conducted in the context of a formal review, initiated by the European Commission under Article 20 of Regulation (EC) No 726/2004/EC. The Committee will make recommendations on whether the marketing authorisation of Rotarix should be maintained, changed, suspended or revoked.
7. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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