



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency statement on new information on Rotarix oral vaccine

The European Medicines Agency is aware of new information reported by the manufacturer of Rotarix, GlaxoSmithKline Biologicals, relating to the unexpected presence of DNA of a non-disease causing viral strain in batches of the oral vaccine. Through its own tests, the company has confirmed the finding of DNA originating from porcine circovirus type 1. This virus is commonly found in certain meat and other food products, and is not known to cause disease in either animals or humans.

An initial review by the Agency's Committee for Medicinal Products for Human Use (CHMP) considered these findings on 17 March 2010 and concluded that no action was necessary at this point. The Committee stresses that the findings do not present a public health threat. It also noted that there have been no safety signals reported with the vaccine that suggest otherwise.

It is nonetheless clear that viral DNA should not be present in the vaccine and that its source is unclear. The Committee has therefore requested the manufacturer to provide further information as a matter of urgency.

The Agency is working closely on this matter with its international counterparts. A meeting of the CHMP Vaccine Working Party has been called for 23-24 March 2010, with the participation of the WHO, and international regulators including from Canada and the USA. The next steps will be considered at an extraordinary meeting of the CHMP to be held on 25 March 2010.

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

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 WHO pre-qualification programme for vaccines. Some 100,000 children received the vaccine during clinical trials and about 68 million doses have been distributed worldwide to date.



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. 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.
3. 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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