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Press Office

Press release

European Medicines Agency confirms positive benefit-risk balance of Rotarix

Porcine circovirus type 1 in the oral vaccine poses no risk to public health

Following a review of the oral vaccine Rotarix, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the vaccine continues to have a positive benefit-risk balance and that the presence of a very small amount of viral particles does not present a risk to public health.

Results from a very large clinical study database, together with safety data from millions of children who have already received the vaccine, show no safety concern with the vaccine.

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 review of Rotarix was initiated after the unexpected detection of DNA of Porcine circovirus type 1 (PCV-1) in the vaccine. PCV-1 is commonly found in certain meat and other food products, and is not known to cause any disease in either humans or animals.

Data from tests carried out by the manufacturer, GlaxoSmithKline Biologicals S.A., showed that the vaccine contained only very small amounts of live PCV-1. The viral particles may have always been present in the vaccine, and have been found in the raw material used to make the vaccine. Their presence was detected only now because of the emergence of new technology.

The Committee concluded that the detection of PCV-1 did not change the benefit-risk balance of Rotarix, and noted that the vaccine is effective in preventing rotavirus infections which are responsible for half a million deaths each year, mostly in developing countries.

However, since PCV-1 should not be present in the Rotarix vaccine, the manufacturer has proposed measures to manufacture the vaccine free of the virus.

The CHMP's recommendation has been forwarded to the European Commission for the adoption of a binding decision.



Notes

1. More information on this review is available in the document: [Questions and answers on the review of Rotarix \(rotavirus vaccine, live\)](#).
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. Rotarix was approved in the European Union (EU) in February 2006. It is not usually part of Member States' childhood vaccination schedules, but is approved in all EU Member States. As for many vaccines, Rotarix is given according to official recommendations in line with vaccination programmes in the different Member States.
4. 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 review of Rotarix was conducted in the context of a formal review, initiated by the European Commission under Article 20 of Regulation (EC) No 726/2004/EC.
6. 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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