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Questions and answers on the review of Rotarix (rotavirus vaccine, live)

Outcome of a procedure under Article 20 of Regulation (EC) No 726/2004

The European Medicines Agency has completed a review of Rotarix at the request of the European Commission, following the discovery of DNA from porcine circovirus type 1 (PCV-1) in the vaccine. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that there are no safety concerns with the use of Rotarix.

What is Rotarix?

Rotarix is an oral vaccine that is used in babies from six weeks of age to protect against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infections. It contains a live attenuated (weakened) form of the human rotavirus (RIX4414 strain).

When an infant is given the vaccine, the immune system (the system that fights diseases) recognises the weakened virus in the vaccine as 'foreign' and makes antibodies against it. An antibody is a type of protein that can neutralise or destroy an antigen, such as a virus. After vaccination, the immune system is able to produce antibodies more quickly when it is exposed to the virus again. This helps to protect against gastroenteritis caused by rotavirus.

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 Member States. The vaccine is widely used outside the EU and is part of the World Health Organization (WHO) prequalification programme for vaccines.

Why was Rotarix reviewed?

The review followed the discovery of DNA of PCV-1 in the vaccine. This was first reported in an article published in March 2010[1]. The CHMP noted at the time that the findings did not present a public health threat because PCV-1 does not cause disease in humans or animals and is commonly found in meat and other foods that are widely consumed.

[1] Viral Nucleic Acids in Live-Attenuated Vaccines: Detection of Minority Variants and an Adventitious Virus. Victoria JG, Wang C, Jones MS, Jaing C, McLoughlin K, Gardner S and Delwart EL. *J Virol. 2010 Jun;84(12).* http://jvi.asm.org/cgi/content/short/84/12/6033

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The PCV-1 material may have always been present in the vaccine and was only detected through the use of new technology. As the vaccine is made using animal cell lines, it is likely that the viral material was in the raw materials used to prepare the original cells. To date around 68 million doses of Rotarix have been distributed worldwide and the vaccine has been shown to be effective and safe.

After the Committee consulted with the European Commission on the issue, the Commission asked the CHMP to give an opinion on whether the marketing authorisation for Rotarix should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CHMP reviewed?

The CHMP reviewed data from tests carried out by the company that makes Rotarix to determine the nature and quantity of the viral material in the vaccine. The Committee also considered the available safety data for Rotarix.

What are the conclusions of the CHMP?

The Committee noted that Rotarix contains a very small amount of the PCV-1 virus. Based on the fact that PCV-1 does not cause any disease and on the safety data from the millions of children who have already received the vaccine, the Committee concluded that the detection of PCV-1 did not change the vaccine's benefit-risk balance. The Committee also noted that the vaccine is effective at preventing rotavirus infections, which are responsible for half a million deaths each year, mostly in developing countries.

The CHMP concluded that the benefits of Rotarix continue to outweigh its risks, and recommended that the marketing authorisation be maintained. The Committee also approved the company's plans to remove the virus from the manufacturing process.

What are the recommendations for parents and carers?

- Parents are reminded that the detection of PCV-1 in Rotarix has not made the vaccine any less safe.
- Parents are also reminded that the vaccine is effective at preventing potentially fatal rotavirus infections. It is therefore not advisable to avoid vaccination on the basis of these PCV-1 findings.
- Parents who have any questions or concerns should speak to their doctor or pharmacist.

What are the recommendations for prescribers?

- Prescribers are reminded that benefits of Rotarix continue to outweigh its risks and that the vaccine's safety is unaffected by the PCV-1 findings.
- As for many vaccines, Rotarix is given according to official recommendations in line with vaccination programmes in the different Member States.

A European Commission decision on this opinion will be issued in due course.

See the latest EPAR for Rotarix.