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

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

The European Medicines Agency has completed a review of RotaTeq at the request of the European Commission. This followed the detection of DNA fragments from porcine circovirus (PCV) 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 RotaTeq.

What is RotaTeq?

RotaTeq is an oral vaccine that is used in infants from six weeks of age to protect against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infections.

RotaTeq contains five live rotavirus forms, each carrying a different antigen (G1, G2, G3, G4 and P1[8]). An antigen is a specific structure that the body recognises as 'foreign' and against which it can make an antibody, a special protein that can neutralise or destroy the antigen. RotaTeq contains viruses that carry the antigens for some of the most commonly occurring types of rotaviruses. When a child is given the vaccine, the immune system (the system that fights diseases) makes antibodies against these antigens. If exposed to the viruses in the future, the immune system will be able to make antibodies more quickly. This will help to protect against gastroenteritis caused by rotaviruses that carry the same or very similar antigens.

A marketing authorisation for RotaTeq valid throughout the European Union was granted to Sanofi Pasteur MSD, SNC, in June 2006. The vaccine is not usually part of Member States' childhood vaccination schedules, but is approved in all Member States. The vaccine is widely used in developing countries.

Why was RotaTeq reviewed?

The review of RotaTeq was triggered by the detection of PCV type 1 in batches of another live-virus rotavirus vaccine, Rotarix, which was reported in an article published in March 2010[1]. In May 2010, the manufacturer of RotaTeq also detected fragments of DNA from PCV-1 and 2 but at very low levels.

[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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These levels were near the lower limit of detection of the testing method used. At its May 2010 meeting, the CHMP reviewed these findings and concluded that there was no need to restrict the vaccine's use.

PCV-1 and PCV-2 are commonly found in meat and other foods that are widely consumed. Although PCV-2 can cause a wasting disease in piglets, neither PCV-1 nor PCV-2 causes disease in humans.

To date more than 37 million doses of RotaTeq have been distributed worldwide, and the vaccine has been shown to be effective and safe. The Agency however considered that further in-depth analysis of the issues was appropriate. Consequently, the European Commission asked the CHMP to issue an opinion on RotaTeq and on whether its marketing authorisation should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CHMP reviewed?

The CHMP reviewed data from tests provided by Sanofi Pasteur MSD to determine the nature and quantity of the viral material in the vaccine. The Committee also considered the available safety data for RotaTeq.

What are the conclusions of the CHMP?

The CHMP noted that, although DNA fragments of PCV-2 have been detected in RotaTeq at very low levels, all the tests show that no whole viruses of either PCV-1 or PCV-2 are present in the vaccine. As low levels of PCV-2 DNA fragments do not pose any risk of infection, the Committee concluded that the safety of the vaccine remains the same. 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 RotaTeq continue to outweigh its risks, and therefore recommended that the marketing authorisation be maintained. The Committee also concluded that no changes to the manufacturing of the vaccine are needed, but that the company should take measures to continue to ensure that the vaccine is produced free of PCV.

What are the recommendations for parents or carers?

- Parents are reminded that the detection of fragments of PCV-2 DNA in RotaTeq has not made the vaccine any less safe.
- Parents are also reminded that the vaccine is effective at preventing potentially fatal rotavirus infections and should continue to be used when needed.
- 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 RotaTeq continue to outweigh its risks and that the vaccine's safety is unaffected by the PCV-2 findings.
- As for many vaccines, RotaTeq 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.

The current European public assessment report for RotaTeq can be found on the Agency's website.