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Press Office

Press release

European Medicines Agency confirms positive benefit-risk balance of RotaTeq

Very low levels of porcine circovirus type 2 DNA fragments in the oral vaccine pose no risk to public health

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

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

Safety data from millions of children who have already received the vaccine show no safety concern with the vaccine. The vaccine is effective in preventing rotavirus infections which are responsible for half a million deaths each year, mostly in developing countries.

The review of RotaTeq was initiated after the unexpected detection of DNA fragments of porcine circovirus (PCV) in the vaccine. PCV-1 and PCV-2 are commonly found in meat and other foods that are widely consumed. Neither virus causes disease in humans, but PCV-2 can cause a wasting disease in piglets.

Data from tests provided by Sanofi Pasteur MSD showed that the vaccine contains only very low levels of PCV-2 fragments and that no whole viruses of either PCV-1 or PCV-2 are present in the vaccine, so it does not pose any risk of infection.

The Committee concluded that the detection of very low levels of PCV-2 fragments did not change the benefit-risk balance of RotaTeq.

Sanofi Pasteur MSD will take measures to continue to ensure that the vaccine is produced free of PCV.

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

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Notes

1. More information on this review is available in the document: Questions and answers on the review of RotaTeq (rotavirus vaccine, live, oral).
2. RotaTeq contains five live human rotavirus strains that carry the antigens for some of the most commonly occurring types of rotaviruses.
3. RotaTeq was approved in the European Union in June 2006. The marketing authorisation holder is Sanofi Pasteur MSD, SNC. RotaTeq is not usually part of Member States' childhood vaccination schedules. As with many vaccines, RotaTeq is given according to official recommendations in line with vaccination programmes in the different Member States.
4. The vaccine is mainly used outside of the European Union and is part of the World Health Organization (WHO) prequalification programme for vaccines. Over 37 million doses of RotaTeq have been distributed worldwide to date.
5. More information on Rotateq is available in the European Public Assessment Report (EPAR).
6. The review of Rotateq was conducted in the context of a formal review, initiated by the European Commission under Article 20 of Regulation (EC) No 726/2004/EC.
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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