

Vaccines, Blood & Biologics

Additional Information for Healthcare Providers and Public Health Professionals

Updated May 14, 2010

What information is available to share with parents about the findings of PCV or PCV DNA in rotavirus vaccines?

Based on careful evaluation of a variety of scientific information, FDA has determined it is appropriate for clinicians and health care professionals to resume the use of Rotarix and to continue the use of RotaTeq.

FDA has no evidence that either PCV1 or PCV2 poses a safety risk in humans, and notes that neither is known to cause infection or illness in humans. In addition, both rotavirus vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of recipients.

The benefits of the vaccines are substantial, and include prevention of hospitalization for severe rotavirus disease in the U.S. and of death in other parts of the world. FDA has posted [information for parents and caregivers](#)¹ on its web site.

I have a supply of either Rotarix or RotaTeq vaccine in my medical practice. Can I use it?

Yes, FDA has determined it is appropriate for clinicians and public health professionals in the United States to use these vaccines.

Is there any medical follow-up needed for children who have received the Rotarix or RotaTeq vaccine?

FDA does not believe medical follow-up is warranted for children who have been vaccinated with Rotarix and RotaTeq vaccines. Extensive studies, including placebo-controlled, randomized clinical studies involving tens of thousands of vaccine recipients, support the safety and effectiveness of the vaccine. While the agency learned more about the situation, FDA made the recommendation to temporarily suspend the use of Rotarix.

Will the prescribing information be updated to reflect the presence of PCV and PCV DNA in the vaccines?

FDA is working with both vaccine manufacturers (GlaxoSmithKline and Merck) to update the labeling for both Rotarix and RotaTeq vaccines to include information about the presence of PCV1 (Rotarix) and DNA from PCV1 and PCV2 (RotaTeq) in the vaccines. The patient labeling will also be revised to include this information. FDA is also working with the Centers for Disease Control and Prevention to update the Vaccine Information Statement for rotavirus vaccines.

Was FDA's recommendation to temporarily suspend use of Rotarix due to safety concerns?

No. FDA made the recommendation while the agency learned more about the situation.

Based on what we know at the current time, the presence of PCV and PCV DNA is not a safety risk. FDA has no evidence that either PCV1 or PCV2 poses a safety risk in humans, and notes that neither is known to cause infection or illness in humans. In addition, both rotavirus vaccines have strong safety records.

How can I find out more?

FDA will keep healthcare providers and public health professionals updated on the situation at www.fda.gov².

Links on this page:

1. <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm>
2. <http://www.fda.gov/>