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Early Communication on Rotarix Vaccine

Summary

FDA is updating clinicians on information that recently has become available about Rotarix, a vaccine used to prevent rotavirus disease. FDA has learned that DNA from porcine circovirus type 1 (PCV1) is present in Rotarix. There is no evidence at this time that this finding poses a safety risk. While the agency is learning more about the situation, FDA is recommending that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix. FDA will keep the public and the clinical community updated through www.fda.gov (<https://wayback.archive-it.org/7993/20170113152120/http://www.fda.gov/>) and other communications.

Background

Rotavirus disease causes the deaths of more than 500,000 infants around the world each year, primarily in low- and middle-income countries. Before the introduction of vaccination, the disease caused more than 50,000 hospitalizations and several dozen deaths in the United States each year.

Rotavirus vaccines are given by mouth to young infants to prevent rotavirus disease, which can cause severe diarrhea and dehydration. There are two licensed rotavirus vaccines in the United States: Rotarix (GlaxoSmithKline) and RotaTeq (Merck).

FDA has learned that DNA from porcine circovirus type 1 (PCV1) is present in Rotarix. This finding was reported to FDA by GlaxoSmithKline, based on work originally performed by an independent U.S. academic research team using a novel technique to look for viruses. GlaxoSmithKline conducted additional studies and confirmed that DNA from PCV1 is present in the finished Rotarix vaccine, as well as in the cell bank and seed from which the vaccine is derived. This confirms that the DNA from PCV1 has been present since the early stages of the vaccine's development, including during clinical studies.

There is no evidence at this time that DNA from PCV1 in Rotarix poses a safety risk. PCV1 is not known to cause any disease in animals or humans. Rotarix has been extensively studied, before and after approval, and found to have an excellent safety record.

FDA Actions

FDA has carefully reviewed available data on the presence of DNA from PCV1 in Rotarix. Through its own laboratory studies, FDA has confirmed the presence of DNA from PCV1 in this vaccine. FDA has also consulted with experts in PCV1 and communicated with the World Health Organization and counterpart regulatory agencies in other countries.

FDA is obtaining additional information about the presence and origins of DNA from PCV1 in Rotarix. This will include making a determination of whether intact virus (as opposed to DNA fragments) is present.

RotaTeq is made using a different process from the Rotarix vaccine. Preliminary studies on RotaTeq, both by the academic research team and by FDA, have not shown the presence of DNA from PCV1. FDA is working with Merck to confirm these findings.

Within approximately four to six weeks, FDA will convene an advisory committee to review the available data and make recommendations on the licensed rotavirus vaccines. FDA will also seek input on the use of new techniques for identifying viruses in vaccines.

Recommendations to Clinicians and Public Health Professionals

The benefits of vaccination against rotavirus disease are substantial, both in the developing world and in developed countries. The safety record of both rotavirus vaccines is excellent.

FDA is continuing to investigate the finding of DNA from PCV1 in Rotarix. While FDA is gathering additional information to present to its expert advisory committee in four to six weeks, the agency recommends that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix.

Because available evidence supports the safety of Rotarix, no medical follow-up is needed for patients who have been vaccinated with Rotarix.

The agency anticipates that following the advisory committee meeting, based on expert input and additional review, FDA will make further recommendations on the use of the two licensed rotavirus vaccines in the United States. FDA will keep the public and clinical community updated through www.fda.gov (<https://wayback.archive-it.org/7993/20170113152120/http://www.fda.gov/>) and other communications.

Additional information for healthcare providers is available [here \(https://wayback.archive-it.org/7993/20170113152120/http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205548.htm\)](https://wayback.archive-it.org/7993/20170113152120/http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205548.htm).

Resources for You

- [Update on Rotavirus Vaccine](https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm)
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- [Rotarix](https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm133920.htm)
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