



The FDA Safety Information and Adverse Event Reporting Program

Rotarix

[03/22/2010]

美國近期發布葛蘭素史克大藥廠（GSK）產製之人類輪狀病毒疫苗Rotarix 之安全資訊，發現該疫苗中含有第一型豬環狀病毒去氧核糖核酸（PCV-1 DNA）。PCV-1 經常發現於豬肉製品中。依據現有資料無法證實PCV-1 對於人類有致病風險，但建議暫停使用該輪狀病毒疫苗，同時要求GSK 應儘速釐清該病毒對於人的風險。世界衛生組織對此發現未做任何建議，但提醒醫師應審慎評估接種輪狀病毒疫苗的風險效益。

Rotarix

Audience: Pediatric and family practice healthcare professionals, public health professionals
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FDA is recommending that healthcare professionals temporarily suspend the use of Rotarix, a vaccine used to prevent rotavirus disease. FDA's recommendation is a precaution taken while the agency learns more about the situation.

FDA has learned that DNA from porcine circovirus type 1 (PCV1) is present in Rotarix. PCV1 is not known to cause disease in humans. There is no evidence at this time that this finding poses a safety risk. Because available evidence supports the safety of Rotarix, no medical follow-up is needed for patients who have been vaccinated with Rotarix.

There are two licensed vaccines for rotavirus in the United States: RotaTeq and Rotarix. For children who have received one dose of Rotarix, CDC advises that clinicians can complete the series with RotaTeq for the next two doses.

Additional information, including information for healthcare professionals and parents, is provided in the document below.