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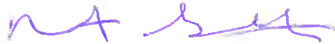


ARNOLD SCHWARZENEGGER
Governor

March 23, 2010

IZB-FY0910-6

TO: California Vaccines for Children (VFC) Program Providers

FROM: Robert Schechter, M.D., Acting Chief 
Center for Infectious Diseases
Division of Communicable Disease Control, Immunization Branch

SUBJECT: Temporary Suspension of Rotarix®

Background

As a precaution, the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are recommending that providers in the United States temporarily suspend their use of the GSK rotavirus vaccine, *Rotarix*®, for at least the next 4-6 weeks.

Using a new lab technique, an independent academic research team has detected DNA from a pig virus (*porcine circovirus type 1*) in *Rotarix*® but has not confirmed whether infectious virus is actually present in the vaccine. There is no evidence yet that this laboratory finding poses a safety risk. This virus has been commonly detected in food products, and is not known to cause disease in either animals or humans. Moreover, *Rotarix*® has been used widely around the world in recent years with a good track record for safety in the infants receiving it. (After its initial review of these findings, the European Medicines Agency, a counterpart to the FDA, has not suspended the use of *Rotarix*® in the European Union at this time, in contrast to FDA.)

FDA is conducting a thorough investigation on this issue and expects to convene an expert advisory committee to review the investigation over the next 4-6 weeks. Until then, VFC providers should continue to immunize infants against rotavirus with the other licensed rotavirus vaccine, *RotaTeq*® (Merck). Preliminary studies have found no circovirus DNA in the *RotaTeq*® rotavirus vaccine.

Please note that porcine circovirus type 1 is sometimes abbreviated as PCV1, while the abbreviation for the new 13-valent pneumococcal conjugate vaccine has been PCV13. Despite this similarity in abbreviations, circovirus is *not* related to pneumococcal vaccines.

Vaccine Ordering

If you have *Rotarix*® on hand, please mark the doses "Do Not Use" and keep them stored properly in your refrigerator to maintain their potency until the advisory committee and FDA recommend that they can be used again. One exception: If you have doses of *Rotarix*® that are set to expire before April 15, you may return them now using the normal procedure for returning

non-viable vaccine to McKesson Specialty. The return form with instructions can be found at <http://www.eziz.org/PDF/RETURN-TRANSFER.pdf>.

Please use the VFC order form as needed to place a supplemental order for RotaTeq®. Please keep in mind that this is a 3 dose series, and not 2 doses like Rotarix®. If you recently ordered other vaccines, you may submit an order for just RotaTeq®. If you are scheduled to order all vaccines in the next 1-2 weeks, please go ahead and place your full order now. If you submitted an order for Rotarix® in the last several days (since 3/18) the VFC office will automatically substitute RotaTeq®.

Administration of RotaTeq®

RotaTeq® is a three-dose series recommended at 2, 4, and 6 months of age. The vaccine is provided in ready to use, plastic, latex-free liquid tubes. It should be administered as soon as possible after being removed from refrigeration. To administer RotaTeq®:

- Tear open the pouch and remove the dosing tube.
- Clear any vaccine from the dispensing tip by holding the tube vertically and tapping the cap.
- Puncture the dispensing tip by screwing the cap clockwise until it becomes tight then remove the cap by turning it counterclockwise.
- Administer the dose by gently squeezing the vaccine into the infant's mouth toward the inner cheek until the dosing tube is empty.

If your patients received one dose of Rotarix®, they should be given two additional doses of RotaTeq® to finish the series. If your patients received the full-2 dose series of Rotarix®, there is no need for them to be revaccinated.

Questions

If you have any questions, please call your VFC Representative or the VFC Program at 877-243-8832 (877-2GET-VFC). You can also visit our website at www.eziz.org.

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