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State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

July 1, 2009

TO: California Physicians Administering Japanese Encephalitis Virus Vaccine Inactivated (JE-VAX®)

FROM: Mark B. Horton, MD, MSPH
State Public Health Officer

SUBJECT: Continued Use of Japanese Encephalitis Virus Vaccine Inactivated
From July 1, 2009 – June 30, 2010

SUMMARY

Since July 1, 2006, California law [Health and Safety Code Section 124172 subdivision (a)] provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances. The Secretary of the California Health and Human Services Agency has again granted a twelve month exemption to this restriction for Japanese Encephalitis Virus Vaccine Inactivated (JE-VAX®) from July 1, 2009 to June 30, 2010. This exemption will allow this vaccine to continue to be administered to children younger than three years old and pregnant women younger than 18 years of age. The exception was granted because of the dangers posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California younger than 18 years of age seeking protection against Japanese Encephalitis. Physicians who wish to protect pregnant women 18 years and older against Japanese Encephalitis should instead consider use of the recently licensed preservative-free Japanese Encephalitis vaccine (IXIARO®, manufactured by Intercell Biomedical and distributed by Novartis Vaccines and Diagnostics, Inc.)

Japanese Encephalitis Disease and Vaccine

Japanese Encephalitis, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Since 2005 major outbreaks of Japanese Encephalitis have resulted in illness and death of thousands of persons in India and Nepal. Most persons with encephalitis caused by the Japanese Encephalitis virus either die or have residual neurologic disease. Unimmunized children in affected areas are at highest risk of Japanese Encephalitis, while infection during pregnancy may cause miscarriage. There is currently no treatment for Japanese Encephalitis.

The federal Food and Drug Administration (FDA) has licensed two vaccines against Japanese Encephalitis for use in the United States:

1) Japanese Encephalitis Virus Vaccine Inactivated, whose trade name is JE-VAX®. It is manufactured in Japan by The Research Foundation for Microbial Diseases of Osaka University (“BIKEN®”) and distributed in the United States by sanofi pasteur, Inc.

Japanese Encephalitis Virus Vaccine Inactivated contains thimerosal as a preservative at a final concentration of 0.007%. The dose for children from 1- <3 years of age is 0.5 milliliters, which contain 17.5 micrograms of mercury. The dose for persons three years of age and older is 1.0 milliliters, which contain 35 micrograms of mercury. The mercury content of Japanese Encephalitis Virus Vaccine Inactivated exceeds the limit set by California Health and Safety Code Section 124172 subdivision (a) of 0.5 micrograms of mercury per 0.5 milliliter dose for vaccines (other than influenza vaccine) administered to young children and pregnant women in California on or after July 1, 2006. The bill which created this law, AB 2943 (Pavley, Chapter 837, Statutes of 2004), was signed in 2004 by Governor Arnold Schwarzenegger to ensure that pregnant women and children under age three have access to mercury-free vaccines.

2) Japanese Encephalitis Vaccine, Inactivated, Adsorbed whose trade name is IXIARO®. It is manufactured in England by Intercell Biomedical and distributed in the United States by Novartis Vaccines and Diagnostics, Inc. This vaccine was licensed by FDA in March 2009 for use in persons 18 years and older. It is free of preservatives, including those that contain mercury.

The national Advisory Committee on Immunization Practices recommends that Japanese Encephalitis Virus Vaccine Inactivated should be offered to persons spending a month or longer in endemic areas during the transmission season, to travelers to areas experiencing epidemic transmission and to persons whose activities, such as extensive outdoor activities in rural areas, place them at high risk for exposure. (<http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.)

Exemption to California Mercury Free Vaccine Act

California Health and Safety Code Section 124172 subdivision (c) permits the Secretary of the Health and Human Services Agency to exempt the use of a vaccine from section 124172 subdivision (a) “if the secretary finds, and the Governor concurs, that...shortage of supply of a vaccine that would prevent children under three years of age and knowingly pregnant women from receiving the needed vaccine,” making “necessary the administration of a vaccine containing more mercury than the maximum level set forth in subdivision (a)...” (http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_2901-2950/ab_2943_bill_20040928_chaptered.html)

Continued Use of Japanese Encephalitis Virus Vaccine Inactivated
From July 1, 2009 – June 30, 2010
Page 3
July 1, 2009

Because of the dangers posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California persons younger than 18 years seeking protection against Japanese Encephalitis virus, an exemption has been granted again from California Health and Safety Code Section 124172 subdivision (a) for Japanese Encephalitis Virus Vaccine Inactivated for the period of July 1, 2009 through June 30, 2010. This vaccine may continue to be administered, as permitted by other State and federal laws, to children younger than three years old and women who are pregnant and younger than 18 years.

For additional information about this topic, please contact the California Department of Public Health Immunization Branch at (510) 620-3737 or www.getimmunizedca.org.

cc: DHS Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators