



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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DECLARATION OF VACCINE SHORTAGE AND SUSPENSION OF RCW 70.95M.115(1) FOR JAPANESE ENCEPHALITIS VIRUS VACCINE INACTIVATED (JE-VAX<sup>®</sup>)

**WHEREAS** RCW 70.95M.115 prohibits vaccinating a person who is known to be pregnant or under three years of age with a vaccine that contains more than 0.5 micrograms thimerosal per 0.5 milliliter dose in Washington State, except for influenza vaccine which is limited at 1.0 microgram per 0.5 milliliter dose. RCW 70.95M.115(3) authorizes the secretary of the department of health to temporarily suspend those limits if there is an outbreak of vaccine-preventable disease or a shortage of vaccine that complies with the limits.

Most vaccines approved for use in the United States either do not contain thimerosal, or have thimerosal-free alternatives. In the case of vaccine for Japanese encephalitis, there is no thimerosal-free alternative for children under seventeen years of age. This, combined with the limitations imposed by RCW 70.95M.115(1), has resulted in no Japanese encephalitis vaccine being available to children under three years of age in Washington State.

Japanese encephalitis is a serious infection caused by a virus. It occurs throughout rural parts of Asia and is spread through the bite of infected mosquitoes. Infected mosquitoes then transmit the virus to humans and animals through the feeding process. It cannot be spread directly from contact with another person.

In most cases, Japanese encephalitis causes mild fever and headache and may be asymptomatic. Severe infections do occur, particularly with encephalitis itself, or swelling of the brain. Other symptoms of severe infection are high fever, neck stiffness, stupor, disorientation, abnormal movements, occasional convulsions, coma and paralysis. Fifty percent of those infected with the disease experience lifelong complications (e.g. neurological disease) and thirty percent of those suffering severe infection die. Unimmunized children are at the highest risk of becoming infected.

There is currently no known treatment once infected. Vaccination combined with precaution against mosquito bites are the best method of prevention.

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The United States Food and Drug Administration (FDA) has licensed two vaccines against Japanese encephalitis for use in the United States, going by the trade names of JE-VAX<sup>®</sup> and IXIARO<sup>®</sup>.

JE-VAX<sup>®</sup> has a thimerosal content of 17.5 micrograms per 0.5 milliliter dose, exceeding the limits in RCW 70.95M.115(1) for those under three years of age. This vaccine is not recommended for children younger than one year of age, or women who are pregnant or nursing.


In late March, 2009, the FDA approved distribution IXIARO<sup>®</sup> vaccine in the United States. Because this vaccine is new to the market its future availability in Washington State is uncertain. IXIARO<sup>®</sup> is not approved for anyone younger than 17 years of age. For pregnant or nursing women, the manufacturers recommend they discuss with their physicians the benefits and risks of IXIARO<sup>®</sup> vaccine before traveling.

IXIARO<sup>®</sup> does not contain thimerosal and, therefore, does provide a thimerosal-free alternative for vaccination against Japanese encephalitis. However, because IXIARO<sup>®</sup> is not licensed for anyone younger than 17 years of age, JE-VAX<sup>®</sup> remains the only Japanese encephalitis vaccine available in the United States to children between one to three years of age.

**NOW, THEREFORE**, I, Mary Selecky, Secretary of the Department of Health, under RCW 70.95M.115(3), and under the circumstances set forth above, declare that there is a shortage of vaccine for Japanese encephalitis that complies with the limits in RCW 70.95M.115(1). The Japanese Encephalitis virus poses grave health risks to Washingtonians living or traveling in affected areas. Although JE-VAX<sup>®</sup> exceeds the thimerosal limits in state law, there is no alternative vaccine available for residents of Washington under 17 years of age seeking protection against Japanese encephalitis.

I also, under RCW 70.95M.115(3), temporarily suspend the thimerosal limits imposed by RCW 70.95M.115(1) on use of the JE-VAX<sup>®</sup> vaccine to allow children one to three years of age access to protection against the Japanese encephalitis virus they would not otherwise have. This suspension will last for a period of one year, beginning July 1, 2009. The department has prepared a notice document that can be provided to persons known to be pregnant or lactating or the legal guardians of children under eighteen years old regarding the thimerosal content of JE-VAX<sup>®</sup>, as required by RCW 70.95M.115(3). At the end of this one year period, I will reassess the availability and supply of vaccine for the Japanese encephalitis virus to determine if it is necessary to continue this declaration and suspension.

Signed this 16 day of June, 2009 at Olympia, Washington

  
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Mary C. Selecky, Secretary  
Washington State Department of Health