

USAMMDA INFORMATION PAPER

PRODUCT: TICK-BORNE ENCEPHALITIS VIRUS VACCINE

DESCRIPTION: Tick-borne Encephalitis (TBE) is a viral infection of the central nervous system transmitted to people by infected ticks. This disease is endemic in several European countries, Russia, and China. Transmission is seasonal and occurs between April and November, particularly in forest and rural areas. The incubation period averages 7-14 days, followed by 1-8 days of fever and flu-like symptoms. Encephalitis occurs in up to 30 percent of infected individuals requiring many weeks of hospitalization and rehabilitation. Mortality is 1-2 percent in general, but can be as high as 23 percent in the Far East. Once infected, there is no effective curative treatment, only supportive care. However, a TBE virus vaccine has been used in Europe for over 20 years to prevent illness due to TBE virus infection. The vaccine is licensed for use in Europe, but it is not licensed in the U.S.

PROGRAM RELEVANCE to the ARMY: The TBE vaccine supports the core Mission of the Army, Army Transformation, and Force Operating Capability MD 97-007 (Preventive Medicine). In addition, the National Institute of Allergy and Infectious Disease (NIAID) identifies TBE as a Category C Priority Pathogen for development of biodefense counter measures. The TBE vaccine increases the survivability and sustainability of forces in regions of the world where TBE is endemic, thereby directly enhancing Current Force and Future Force operations. The TBE vaccine is key to maintaining OPTEMPO by providing protection for individual personnel, thus enabling continued operations despite the presence of endemic disease.

ISSUES/ACTIONS:

- The TBE vaccine effort has remained unfunded due to limited availability of development funds and the relatively low priority of TBE against other infectious disease threats.
- Commercial firms have not been interested in pursuing Food and Drug Administration (FDA) licensure without financial support from the U.S. Government because of the limited U.S. market for this vaccine and the prohibitive clinical trial costs required to support FDA licensure.
- Industrial partner submitted NIAID Challenge Grant application that, should it be approved, would support FDA licensure effort.
- Policy guidance for TBE vaccination of U.S. Forces in anticipation of Department of Defense usage of an FDA licensed TBE vaccine was sought from the Office of Force Health Protection and Readiness. The policy adopted will have an impact on the number of doses required and will clarify anticipated vaccine usage by U.S. Forces.

BPL# 335

DA PROJECT/TASK: Infectious Diseases

PE/PROJ 643807.849TJ

MAMP RANK: 20/36

ARMY ORD: Tick-Borne Encephalitis Vaccine

Approved 9 August 1994

CARDS #: 1430

SCHEDULE:

MS B TBD

MS C (2-3 Yrs After MS B)

For additional information contact:

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