



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

May 18, 2011

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Department of Defense Participation in IXIARO[®] Japanese Encephalitis Vaccine
Post-Licensure Requirements

IXIARO[®], which is manufactured by Intercell AG, will soon become the only Japanese encephalitis vaccine licensed by the U.S. Food and Drug Administration (FDA). There is no specific treatment available for Japanese encephalitis disease, so pre-exposure protection against the disease is essential. The FDA identified three post-marketing commitments for Intercell AG to complete for continued licensure of IXIARO[®].

Two of the three commitments involve Department of Defense (DoD) populations, and therefore, require DoD's participation. The first is an active surveillance study for adverse events among 20,000 Service members after vaccination with IXIARO[®], and the second is an electronic surveillance study of female Service members who were inadvertently vaccinated while pregnant. The Military Vaccine Agency will coordinate DoD efforts to meet requirements in support of the studies with the manufacturer, and the FDA, and will perform active electronic surveillance using the Defense Medical Surveillance System database and DoD electronic health record in collaboration with Intercell AG.

Three conditions are important for DoD's collaboration and participation in the specific post-licensure requirements: (1) Studies will be conducted in compliance with all human research subject protection rules and FDA regulations; (2) Intercell AG is responsible for funding activities that are beyond the current mission requirements of participating DoD organizations; and (3) the primary mission of participating DoD organizations will not be adversely affected.

Preserving the health and safety of our Service members is our top priority. Through participation with the manufacturer in these post-marketing requirements, DoD can better understand the safety profile of IXIARO[®]. This will, in turn, enhance the effectiveness of DoD's vaccination efforts and the national defense preparedness posture. We endorse efforts between DoD and the vaccine manufacturer, Intercell AG, for participation in IXIARO[®] Japanese

encephalitis vaccine post-licensure requirements, and request that the Services support the efforts in meeting this goal. The point of contact for this matter is COL James Boles, who may be reached at (703) 578-8444, or James.Boles@ha.osd.mil.

A handwritten signature in black ink, appearing to read "Jonathan Woodson". The signature is fluid and cursive, with the first name "Jonathan" being more prominent than the last name "Woodson".

Jonathan Woodson, M.D.

cc:

Commandant of the U.S. Coast Guard
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director, Military Vaccine Agency