



HEALTH AFFAIRS

## OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

JPMPG

12 August 2007

MEMORANDUM FOR Deputy Assistant Secretary of Defense for Force Health Protection and Readiness and Director, Deployment Health Support

SUBJECT: Joint Preventive Medicine Policy Group Recommendation Regarding the Use of Tubersol as the Preferred Brand of Tuberculin

### 1. References:

a) Presentation on Tubersol vs Aplisol and Investigation of a Potential Outbreak of Tuberculosis Among Troops in Afghanistan, 2005 by Lisa Keep, MD, MPH, FACPM, COL, MC, USA to the Joint Preventive Medicine Policy Group (JPMPG), 17 May 2007.

b) Taylor Z, Nolan CM, Blumberg HM. Controlling tuberculosis in the United States. Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR Recomm Rep.* Nov 4 2005;54(RR-12):1-81.

c) Targeted tuberculin testing and treatment of latent tuberculosis infection. American Thoracic Society. *MMWR Recomm Rep.* Jun 9 2000;49(RR-6):1-51.

d) Diagnostic Standards and Classification of Tuberculosis in Adults and Children. *Am J Respir Crit Care Med.* Apr 2000;161(4 Pt 1):1376-1395.

2. On May 17, the Joint Preventive Medicine Policy Group (JPMPG) held its monthly meeting at the Skyline complex. Dr. Lisa Keep, COL, MC, USA, Director, Tropical Public Health at the Uniformed Services University, Bethesda, MD, briefed the policy group on the current status of false positive tests for latent tuberculosis associated with Aplisol (Parkedale Pharmaceuticals, Rochester, MI) brand tuberculin including an investigation of a potential outbreak of tuberculosis among troops in Afghanistan in 2005. This briefing assisted the policy group in formulating a recommendation on the preferred use of Tubersol (Sanofi Pasteur Limited, Toronto, Ontario, Canada) brand as the preferred tuberculin used by the U.S. Military.

3. The threat of tuberculosis is a serious public health and force health protection issue within the U.S. Military that requires surveillance, treatment, and control. Skin testing with intradermal purified protein derivative (PPD) identifies persons latently infected with *Mycobacterium tuberculosis* and is the cornerstone for investigation of potential outbreaks of tuberculosis. Two brands of PPD are currently available in the United States: Aplisol and Tubersol.

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4. Multiple reports in the medical literature have associated Aplisol with 'outbreaks' (increased annual conversion rates of one to four percent) of positive tuberculin skin tests (TSTs) in low risk populations that are interpreted as negative when the same individuals are retested with Tubersol. False positive PPD tests conducted with Aplisol may result in nine months of prophylactic Isoniazid (INH) treatment which historically has been associated with a risk of hepatotoxicity of five to 20 cases per 1000 persons receiving treatment and a one to 10 percent case fatality rate.

5. Although current DoD MILVAX pricing places Tubersol as the more costly up-front option (Tubersol at \$1.29 per dose vs Aplisol at \$0.68 per dose), the expense of investigating 'outbreaks' associated with false positive TSTs may eliminate this differential. Particularly among deployed personnel, the resultant clinical follow-up of those undergoing unnecessary prophylactic INH treatment for false positive TSTs consumes valuable and limited medical and public health resources and has the potential to impact mission capability and readiness.

6. After a review and discussion of the available information, the JPMPG makes the following recommendations:

**a. TUBERCULOSIS IS A SERIOUS PUBLIC HEALTH AND FORCE PROTECTION ISSUE WITHIN THE U.S. MILITARY. APLISOL HAS BEEN ASSOCIATED WITH SIGNIFICANTLY ELEVATED FALSE POSITIVE TUBERCULIN SKIN TESTING RATES. THE JPMPG RECOMMENDS THAT TUBERSOL INSTEAD OF APLISOL BE THE PREFERRED BRAND OF TUBERCULIN USED BY THE U.S. MILITARY.**

**b. BASED ON CURRENT INFORMATION, THE JPMPG RECOMMENDS APLISOL USE ONLY BE CONSIDERED DURING CRITICAL SUPPLY SHORTAGES OF TUBERSOL.**



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