THE ASSISTANT SECRETARY OF DEFENSE

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HEALTH AFFAIRS

11 July 2011

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
COMMANDERS OF THE COMBATANT COMMANDS
DIRECTOR, JOINT STAFF

SUBJECT: Policy on the Establishment of Comparability of Foreign Nation Blood Supplies to Food and Drug Administration Compliant Blood Products

This policy memorandum provides guidance on the transfusion of non-U.S. blood products that are transfused overseas to U.S. beneficiaries. This policy augments Health Affairs Policy 10-002, *Policy on the Use of Non-U.S. Food and Drug Administration Compliant Blood Products*, dated March 19, 2010.

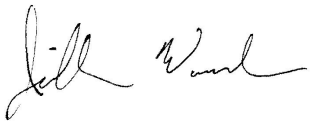
Department of Defense (DoD) health care policy states that beneficiaries must receive medical treatment that meets or exceeds the established "standard of care." In regards to blood transfusions, this means that all transfused blood products collected in the United States must be Food and Drug Administration (FDA)-compliant. FDA-compliant products are fully tested and manufactured by FDA-registered blood establishments in accordance with current, good manufacturing practices. However, FDA-compliant blood products may not always be available for transfusion to DoD beneficiaries when deployed or stationed abroad. Therefore, the use of fully tested non- U.S. blood products at non- U.S. facilities is sometimes necessary to save lives, and may be the only alternative during combat operations or mass casualty events.

The March 19, 2010, Health Affairs *Policy on the Use of Non-U.S. Food and Drug Administration Compliant Blood Products* sets policy for the follow-up and tracking of recipients when non-FDA-compliant blood products are transfused. This same policy also gives the Armed Services Blood Program Office (ASBPO) the responsibility to evaluate foreign nations' blood supplies and deem acceptable, via the Assistant Secretary of Defense for Health Affairs, any country whose blood product manufacturing regulations are comparable to FDA blood product manufacturing regulations. Recipients of blood products manufactured in these countries would then be exempt from the follow-up and tracking described in the March 19, 2010, policy. Any changes in a country's test or practice that degrades or questions whether blood products are FDA-comparable would trigger a re-evaluation of deemed status.

Based on an ASBPO review and evaluation of those countries currently participating in combined operations, fully tested blood products from Canada, the Netherlands, and the United Kingdom are deemed comparable and are exempt from the recipient notification and tracking policies described in the March 19, 2010, Health Affairs *Policy on the Use of Non-U.S. Food and Drug Administration Compliant Blood Products*. Donor screening, collection, and manufacturing of blood products in these countries has been determined to be similar to U.S.

standards. While other countries may also qualify, the volume of blood products transfused to U.S. personnel from the above listed countries is great enough to warrant a waiver and to ease the administrative burden associated with tracking recipients. In any circumstances where blood products from these nations are used before being fully tested, according to the manufacturing nation's prescribed regulations and guidelines, all recipient follow-up requirements will remain mandatory.

The provisions of the policy can be implemented immediately. Feedback, comments, or questions regarding comparability status should be addressed to the Director, Armed Services Blood Program Office, 5109 Leesburg Pike, Falls Church, Virginia 22041-3258, (703) 681-8027, or DSN 761-8027.



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cc:
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