THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

DEC 4 2001

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Policy on the Use of Non-US Food and Drug Administration Licensed Blood Products

DoD policy provides that the standard of care for those beneficiaries who receive a blood transfusion overseas in a DoD medical treatment facility (MTF) shall be equal to that received in a MTF within the United States. Inspection and regulatory requirements over blood and blood products vary widely by country, and even within certain countries, and may not provide for the same level or type of testing as the US Food and Drug Administration (FDA) requires.

This policy memorandum provides guidance on the use of non-FDA licensed blood products overseas in emergencies. It also provides guidance on post-transfusion patient follow-up. The Assistant Secretary of Defense (Health Affairs) "Policy on the Use of Non-DoD, Non-US Food and Drug Administration Licensed Blood Products", dated 12 May 1994, is hereby rescinded. The following policy shall apply to all Department of Defense (DoD) medical facilities. Unified or Specified Commands, and Task Force Surgeons, will report the transfusion of another nation's non-US FDA licensed blood products to the Armed Services Blood Program Office (ASBPO) and the appropriate Service Blood Program Office through the Joint Blood Program Officer.

Blood products received for use in DoD medical treatment facilities (MTFs) from a non-FDA licensed Host Nation or other nations' facilities may be used for the emergent treatment of DoD beneficiaries. Under such circumstances the attending physician must verify and document that the use of untested blood products (by FDA standards) was required for patient care. Each patient transfused with such blood must be tested in the following manner:

- The patients shall have, whenever possible, pre-transfusion blood specimens collected and submitted for testing to determine base-line serological studies for Hepatitis B and C, Human Immunodeficiency Virus, Human T-Cell Lymphotrophic Virus, Syphilis, and other transfusion transmitted diseases as appropriate;
- These patients must be retested at 3 months, 6 months, and 1-year post transfusion;
- If a pre-transfusion specimen cannot be obtained, a blood sample for serological testing shall be collected as soon as possible post transfusion;
- All testing must be completed and documented in the patient's record as soon as practical;

- The Services' Medical Departments are responsible for developing and implementing a process to identify, document, and track post-transfusion testing and care of these patients; and
- Reporting should include national origin of blood, type and number of blood product(s) transfused, and patient name and identification number.

In addition to the testing requirements, the patient shall be given notice, prior to transfusion if feasible or as soon thereafter as possible, that the blood is not FDA licensed, the reasons it is being provided, and the necessary patient follow-up.

A comprehensive audit of non-FDA licensed facilities, that are used as a source of emergency blood or blood products, may be requested by a Unified or Specified Command, or a Task Force Surgeon. These audits will be made available by the Armed Services Blood Program Office (ASBPO) to the Task Force Surgeon or the Unified Command Surgeon for evaluating the safety of local blood supplies. The purpose of these audits is to understand the extent of donor screening and testing as it compares to US standards. The Armed Services Blood Program Office will publish audit procedures in the form of a blood program letter.

These guidelines shall be implemented within 45 days. Please provide implementation documents to the Director, Armed Services Blood Program Office, 5109 Leesburg Pike, Falls Church, VA 22041-3258. For questions regarding this policy please contact Colonel G. Michael Fitzpatrick, Medical Service, United States Army, Director, Armed Services Blood Program at DSN 761-8024, (703) 681-8024, at glen.fitzpatrick@otsg.amedd.army.mil.

William Winkenwerder, Jr., MD

cc:
Surgeon General, U.S. Army
Surgeon General, U.S. Navy
Surgeon General, U.S. Air Force
Deputy Director for Medical Readiness, J-4

PCDOC: 29107

ACTION MEMO

October 12, 2001, 0700

FOR: ACTING ASD (HA) AASD (HA) Action _____

THROUGH: ACTING DASD (HOP) R.O.

FROM: DIRECTOR, ASBPO

SUBJECT: Policy on the Use of Non-US Food and Drug Administration Licensed Blood Products

- The Assistant Secretary of Defense, Health Affairs' "Policy on the Use of Non-DoD, Non-US Food and Drug Administration (FDA) Licensed Blood Products" was published 12 May 1994.

- The policy required DoD to obtain donor specimens from Host Nation facilities in order to perform FDA required testing on DoD patients transfused with non-US FDA licensed blood products

- Obtaining donor specimens from Host Nation facilities is extremely difficult and in most cases unproductive

- The revised policy does not require testing of donor samples from non-FDA licensed facilities. As an alternative, the new policy requires testing of the transfusion recipient. Transfused patients would have pre-transfusion baseline infectious disease testing when possible, and follow-on testing at 3, 6, and 12-month intervals

- Request review and approval of enclosed revised Policy on the Use of Non-US Food and Drug Administration Licensed Blood Products

COORDINATION:

DASD (C&PP): JWS 15 Oct 01
DASD (HB&FP): 10/16/01
CoS (ASD (HA)): _____
OGC revised 11/19/01

RECOMMENDATION: Sign Health Affairs Policy Memorandum (TAB A)

Prepared by: Rebecca V. Sparks, MSC, USN, Deputy Director, Armed Services Blood Program, (703) 681-8024.