## **UNCLAS**

MARADMIN 502/02

MSGID/GENADMIN/CMC WASHINGTON DC/PPO/PLN//

SUBJ/REINTRODUCTION OF THE AMTHRAX VACCINE

REF/A/DOC/DEPSECDEF/28 JUN 02/

AMPN/DEPSECDEF MEMO, SUBJ: REINTRODUCTION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

REF/B/DOC/USECDEF PR/6 AUG 02/

AMPN/USECDEF PR MEMO, SUBJ: ADMINISTRATIVE AND CLINICAL EXECUTION GUIDANCE FOR REINTRODUCTION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

REF/C/DOC/SECNAVINST 6230.4/29 APR 98/

AMPN/DEPARTMENT OF THE NAVY (DON) ANTHRAX VACCINATION

IMPLEMENTATION PROGRAM (AVIP)

REF/D/RMG/BUMED/281959Z FEB 02/

AMPN/BUMED MESSAGE, MEDICAL GUIDANCE FOR IMMUNIZING WOMEN OF CHILDBEARING AGE

REF/E/DOC/ASDFMP MEMO/10 SEP 02/

 $\ensuremath{\mathsf{AMPN/ASDFMP}}$  MEMO, SUBJ: AUTHORIZATION FOR IMMEDIATE USMC AVIP RESUMPTION

REF/F/RMG/SECDEF/OASDPA/282130Z JUN 02/

AMPN/ASDPA MESSAGE, PUBLIC AFFAIRS GUIDANCE RESUMPTION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

REF/G/DOC/SECNAV/ASN(M&RA) MEMO/20 SEP 02/

AMPN/ASN(M&RA) MEMO, SUBJ: APPROVAL OF IMPLEMENTATION PLAN TO RESUME ANTHRAX VACCINE IMMUNIZATIONS

SUBJ: GUIDANCE FOR IMMEDIATE RESUMPTION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) IN ELIGIBLE MARINE CORPS FORCES 1. READ THIS MESSAGE IN ITS ENTIRETY. THIS MESSAGE HAS BEEN COORDINATED WITH OPNAV N931 AND ASDHA, AND HAS BEEN APPROVED BY

ASDFMP (REF E) AND SECNAV (REF G). PURPOSE IS TO ADVISE COMMANDERS:

A. DEPSECDEF HAS ORDERED A THREAT-BASED RESUMPTION OF THE AVIP VIA POLICY MEMOS DATED 28 JUN 2002 (REF A) AND 6 AUG 2002 (REF B). POLICY MEMOS MAY BE VIEWED ON AVIP WEBSITE AT WWW.ANTHRAX.MIL. B. REF C IS CURRENTLY UNDER REVISION AND, WHEN SIGNED, PROVIDES DON EXECUTION GUIDANCE. THIS ALMAR AUTHORIZES IMMEDIATE RESUMPTION OF ANTHRAX VACCINE ADSORBED (AVA) TO INDIVIDUALS ATTACHED TO USMC UNITS CURRENTLY MEETING DEFINITION OF PRIORITY GROUP 2 (SEE PARAGRAPHS 3B AND 4) OR WILL MEET PRIORITY GROUP 2 DEFINITION BASED UPON VALID UNIT EMPLOYMENT PLAN PER MCBUL 3120 CONSOLIDATED DEPLOYMENT SCHEDULE FY 02-04.

## 2. BACKGROUND:

A. ON 31 JAN 02 THE FOOD AND DRUG ADMINISTRATION (FDA) GAVE BIOPORT CORPORATION FINAL APPROVAL TO RESUME THE MANUFACTURE AND DISTRIBUTION OF THE US-LICENSED ANTHRAX VACCINE (AVA) AND RELEASED ADDITIONAL VACCINE FOR USE. THIS RESTORES THE AVAILABILITY OF FDA RELEASED AVA TO DOD.

- B. THE NATIONAL ACADEMY OF SCIENCES' INSTITUTE OF MEDICINE REAFFIRMED AVA SAFETY AND EFFECTIVENESS IN MAR 02 BY PUBLISHING THE FINDINGS OF THEIR TWO YEAR STUDY OF AVA.
- C. CURRENT INTELLIGENCE ASSESSMENTS INDICATE THE ANTHRAX THREAT REMAINS REAL.
- 3. THE INITIAL SCOPE OF AVIP RESUMPTION IS:

- A. PRIORITY GROUP 1: CONTINUE ANTHRAX VACCINATIONS TO DESIGNATED SPECIAL MISSION UNITS, AND PERSONNEL INVOLVED IN RESEARCH AND AVA MANUFACTURING.
- B. PRIORITY GROUP 2: EXPAND VACCINATIONS TO PERSONNEL ASSIGNED TO OR DEPLOYED IN THE HIGHER THREAT AREAS OF SOUTHWEST ASIA (SWA) FOR MORE THAN 15 CONSECUTIVE DAYS. MARINE FORCES AFLOAT ON CONTIGUOUS WATERS IN VICINITY OF ARABIAN PENINSULA (ARABIAN GULF, GULF OF OMAN, GULF OF ADEN, RED SEA) ARE ELIGIBLE, WHILE MOST NAVY FORCES AFLOAT ARE EXCLUDED. PERSONNEL FLYING IN THE AIRSPACE OVER THE HTA SHALL NOT BE VACCINATED UNLESS THEY WILL BE BASED ASHORE FOR 15 OR MORE CONSECUTIVE DAYS.
- C. ACTIVE DUTY AND RESERVE COMPONENT MEMBERS, CIVILIAN PERSONNEL CLASSIFIED AS EMERGENCY-ESSENTIAL, AND CONTRACTOR PERSONNEL CARRYING OUT MISSION ESSENTIAL SERVICES ARE SUBJECT TO THIS POLICY PER REF B. NEAR TERM AVIP IMPLEMENTATION MAY ALSO INCLUDE OTHER PERSONNEL DETERMINED BY THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, IN CONSULTATION WITH THE CHAIRMAN OF THE JOINT CHIEFS OF STAFF, TO BE AT HIGHER RISK FOR EXPOSURE TO ANTHRAX. FOR THOSE PERSONNEL ALREADY DEPLOYED AT THE ISSUANCE OF THIS MARADMIN, WHO WILL ROTATE OUT OF ASSIGNMENT OR RE-DEPLOY FROM HIGHER THREAT AREAS IN 90 DAYS OR LESS, WILL NOT BE REQUIRED TO START VACCINATION AT THIS TIME.
- 4. THE FOUR PRIORITY GROUPS AND THIRTEEN COUNTRIES COMPRISING THE HIGHER THREAT AREAS MAY BE OBTAINED ON SIPRNET VIA THE HQMC/PPO HOMEPAGE WWW.HQMC.USMC.SMIL.MIL/PLN/PLN\_HOME.HTM. 5. LEADERSHIP GUIDANCE:

THE AVIP REMAINS A COMMANDER'S RESPONSIBILITY. IT IS A CRITICAL PART OF THE MARINE CORPS FORCE PROTECTION PROGRAM.

- A. COMMANDERS SHALL ENSURE THAT ALL PERSONNEL UNDER THEIR COMMAND ARE BRIEFED, COVERING TOPICS IN THE MEMBER'S BRIEF, LEADER'S BRIEF, AND TRIFOLD FOUND AT DOD WEBSITE WWW.ANTHRAX.MIL. THE AVIP WEBSITE SHOULD BE PROMOTED AS A VALUABLE RESOURCE TO ALL MEMBERS AND THEIR FAMILIES. LEADERS SHOULD ALSO REVIEW THE COMMANDER'S EDUCATION TOOLKIT AND THE QUESTIONS AND ANSWERS POSTED ON THE WEBSITE, SINCE THESE ARE THE MOST FREQUENTLY ASKED QUESTIONS BY OUR PERSONNEL AND THEIR FAMILIES: REF F MAY ALSO BE UTILIZED FOR THIS PURPOSE. UNIT-WIDE EDUCATION CAMPAIGNS SHOULD OCCUR IN PROXIMITY (DAYS) TO INITIAL UNIT VACCINE ADMINISTRATION. PROFESSIONAL QUALITY TRIFOLD BROCHURES HAVE BEEN DESIGNED ESPECIALLY FOR THIS PURPOSE. THEY MAY BE VIEWED ONLINE UNDER THE POPULAR RESOURCES SECTION OF THE AVIP WEBSITE (WWW.ANTHRAX.MIL/MEDIA/PDF/BROCHURE.PDF). UNIT COMMANDERS, AT THEIR DISCRETION, MAY CONTACT MR. HERMAN HARRIS AT (703) 681-4262, DSN 761-4262, OR HERMAN.HARRIS@AMEDD.ARMY.MIL TO ARRANGE PURCHASE OF QUANTITIES OF THE BROCHURES FOR UNIT EDUCATION.
- B. ADMINISTRATIVE EXEMPTIONS POLICY IS CONTAINED IN REF B. EXEMPTION AUTHORIZATION RESTS WITH THE FIRST GO/FO EXERCISING ADMINISTRATIVE CONTROL (ADCON). COMMANDERS WILL MANAGE IMMUNIZATION REFUSALS AS THEY WOULD ADDRESS ANY REFUSAL TO OBEY A LAWFUL ORDER. 6. MEDICAL GUIDANCE:
- A. MEDICAL PERSONNEL WILL THOROUGHLY UNDERSTAND THE CLINICAL ASPECTS OF THIS VACCINE AND THE POTENTIAL FOR ADVERSE EVENTS AFTER VACCINATION (REF B). MEDICAL PERSONNEL MUST KNOW HOW TO MANAGE THE SPECTRUM OF ADVERSE EVENTS, INCLUDING THE REQUIREMENT TO SUBMIT VACCINE ADVERSE EVENT REPORTS. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, DR. WILLIAM WINKENWERDER, WANTS MEDICAL PERSONNEL TO CLEARLY UNDERSTAND

THEY WILL NOT ONLY ADMINISTER THE VACCINE, BUT WILL BE OUR FRONT LINE RESPONDING TO QUESTIONS AND CONCERNS. THEREFORE, MEDICAL PERSONNEL WILL FAMILIARIZE THEMSELVES WITH ALL AVIP WEBSITE RESOURCES, ESPECIALLY THE CLINICIAN'S TOOLKIT AT

HTTP://WWW.ANTHRAX.MIL/EDUCATION/CLINICIAN/CLINICIANS.ASP.
THE RECENT COMPREHENSIVE REPORT ON ANTHRAX VACCINE SAFETY AND EFFECTIVENESS FROM THE NATIONAL ACADEMY OF SCIENCES' INSTITUTE OF MEDICINE IS OF PARTICULAR NOTE TO MEDICAL PERSONNEL, AND CAN BE READ ONLINE AT <a href="http://www.nap.edu/html/anthrax/index.html">http://www.nap.edu/html/anthrax/index.html</a>.
B. ENSURE APPROPRIATE UNIT MEDICAL PERSONNEL ARE TRAINED IN

B. ENSURE APPROPRIATE UNIT MEDICAL PERSONNEL ARE TRAINED IN STANDARD AUTOMATED MEDICAL SYSTEM (SAMS) IMMUNIZATION TRACKING PROCEDURES

AND HAVE A CURRENT PASSWORD TO ACCESS DEERS IMMUNIZATION TRACKING WEBSITE. DESIGNATED MEDICAL PERSONNEL MUST HAVE ACCESS TO A COMPUTER, A USMC.MIL EMAIL ACCOUNT, AND WORLDWIDE WEB ACCESS. IMMUNIZATION TRACKING IS VITAL FOR ALL ACTIVE AND RESERVE FORCES; IN ADDITION TO RECORDING MEMBER DATA, UNIT DATA, VACCINE LOT NUMBER, AND INJECTION SITE/ROUTE/NUMBER IN SAMS, RECORD THIS SAME INFORMATION IN MEMBER'S HEALTH RECORD AND ON YELLOW SHOT CARD (PHS 731). DOCUMENT PROVISION OF PATIENT EDUCATION IN MEMBER'S HEALTH RECORD. INFORMATION FOR IMMUNIZATION TRACKING CAN BE OBTAINED VIA THE WEBSITE AT HTTPS://IMCENTER.MED.NAVY.MIL/ITS.

- C. PERSONNEL ELIGIBLE FOR VACCINE WITHIN THIS INITIAL PROGRAM SCOPE AND WHO ALREADY HAVE RECEIVED AT LEAST ONE DOSE OF AVA, WILL SIMPLY BEGIN WITH THE NEXT DOSE IN SERIES PER FDA-APPROVED SCHEDULE. THERE IS NO NEED TO RE-START INDIVIDUALS WITH DOSE NUMBER ONE. DOSES WILL NOT BE GIVEN ON A COMPRESSED OR SHORTENED SCHEDULE AS THIS DECREASES EFFECTIVENESS. THESE REQUIREMENTS ARE CONSISTENT WITH FDA REGULATIONS AND GUIDANCE FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S (CDC) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP).
- D. ADDITIONAL DETAILED CLINICAL GUIDANCE IS AVAILABLE IN REF B. THIS GUIDANCE INCLUDES DISCUSSION OF DOSAGE SCHEDULE, MEDICAL SCREENING BEFORE IMMUNIZATION (PROVIDES SAMPLE SCREENING QUESTIONAIRE THAT MAY BE CONSIDERED AND MODIFIED FOR USE), PREGNANCY SCREENING (REF D APPLIES), INJECTION-SITE SELECTION, MEDICAL EXEMPTIONS, AND ADVERSE EVENTS MANAGEMENT.
- E. UNIT MEMBERS CONSIDERED FOR MEDICAL EXEMPTION CODE (MR) (MEDICAL REACTIVE) SHALL BE REFERRED PER CLINICAL MANAGEMENT OF ADVERSE EVENTS GUIDELINES IN REF B FOR APPROPRIATE SPECIALTY EVALUATION PRIOR TO ASSIGNMENT OF MEDICAL EXEMPTION CODE (MR).
- F. VACCINE WILL BE ADMINISTERED ACCORDING TO FDA LABEL REQUIREMENTS. 7. LOGISTICAL GUIDANCE:

A. MARINE FORCES OPCON TO COMUSMARCENT WILL BE SUPPORTED THROUGH COMUSCENTCOM COMPONENT PLANS. INTENT IS TO ENSURE MARINE UNITS ARE UP TO DATE ON AVA STATUS PRIOR TO DEPLOYMENT, INCLUDING PROVISION OF FIRST 3 AVA DOSES TO THOSE CURRENTLY UNIMMUNIZED. AVA WILL BE PROVIDED TO DEPLOYING MARINE CORPS UNITS NO LESS THAN 45 DAYS AND NO MORE THAN 90 DAYS PRIOR TO DEPLOYMENT TO A HIGHER THREAT AREA. B. ENSURE LOGISTICS SUPPORT HAS SUFFICIENT REFRIGERATION CAPACITY TO PRESERVE VACCINE INTEGRITY WITHIN FDA LABEL TEMPERATURE RANGE OF 2-8 DEGREES CENTIGRADE/36-46 DEGREES FAHRENHEIT (DO NOT PUT VACCINE IN DIRECT CONTACT WITH ICE). SUPPORT INCLUDES TWICE DAILY MONITORING OF TEMPERATURE AND BACK-UP POWER SUPPLY. IDEALLY, A 24 X 7 ALARM SYSTEM SHOULD NOTIFY APROPRIATE MEDICAL PERSONNEL. STORE UNOPENED VIALS AT MTFS; AID STATIONS WILL CHECKOUT VACCINE PRIOR TO UNIT

- SHOTEXS AND RETURN UNOPENED VIALS TO THE MTF PRESERVING COLD CHAIN REQUIREMENTS AND VIAL ACCOUNTABILITY. TRANSPORT VACCINES IN VAXI-PACK OR VAXI-COOL CONTAINERS, PREVIOUSLY PROVIDED BY U.S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) FOR MARINE FORCES USE AND CURRENTLY STORED AT MTFS AND CLINICS.
- C. EACH COMMARFOR AND CG MEF WILL DESIGNATE AN AVIP COORDINATOR, WHO WILL PROCURE AVA FOR ELIGIBLE SUPPORTED UNITS UTILIZING USAMMA'S SECURE WEBSITE.
- (1) COMMARFOR AND CG MEF AVIP COORDINATORS MUST FIRST LOG INTO WEBSITE GIVEN BELOW, AND COMPLETE THE REGISTRATION PROCESS. A USER ACCOUNT IS ESTABLISHED ON A SECURE WEBSITE, AND A PASSWORD AND CONFIRMATION WILL BE SENT BACK AFTER APPROVAL FROM NAVAL MEDICAL LOGISTICS COMMAND (NAVMEDLOGCOM) AND HQMC/I&L/LPC-4.
- (2) THE OVERALL GOAL IS TO EXPEDITE THE REQUISITION AND APPROVAL CHAIN FOR AVA REQUIREMENTS. CG MEF AVA COORDINATORS WILL SUBMIT REQUISITIONS ON THE USAMMA WEBSITE FOR THEIR SUPPORTED UNITS, WHILE COMMARFOR AVA COORDINATORS WILL SUBMIT REQUISITIONS ONLY FOR THOSE UNIQUE UNITS NOT ROUTINELY SUPPORTED BY THE CG MEF.
- (3) IOT ENSURE THAT SUPPLY MEETS DEMAND IN THE EARLY PHASES OF RESUMPTION, COMMARFOR AND
- CG MEF COORDINATORS WILL ENSURE THAT ALL REQUISITIONS MEET PRIORITY 2 CRITERIA AND FALL WITHIN THE PROVISION WINDOW DESCRIBED IN PARAGRAPH 7A.
- (4) HQMC WILL SCREEN SUBMITTED REQUISITIONS FOR APPROVAL. NAVMEDLOGCOM WILL COORDINATE HQMC APPROVED REQUISITIONS WITH (USAMMA) FOR VACCINE DISTRIBUTION.
- (5) ANTHRAX VACCINE WILL BE PROVIDED AT NO COST TO UNITS. ANCILLARY SUPPLIES ARE THE RESPONSIBILITY OF THE RECEIVING ACTIVITY.
- (6) REFER TO THE USAMMA WEBSITE FOR MORE INFORMATION (<u>HTTP://WWW.ARMYMEDICINE.ARMY.MIL/USAMMA/ANTHRAX/ANTXHOME.HTM</u>).
- 8. PUBLIC AFFAIRS GUIDANCE (PAG)
- A. PUBLIC AFFAIRS OFFICES ARE EXPECTED TO LOCALIZE AVA STORIES. ENCOURAGE ARTICLES IN BASE NEWSPAPERS AND INSTALLATION WEBSITES THAT LIST PLACES, POC'S AND PHONE NUMBERS WHERE MORE INFORMATION AND BE OBTAINED.
- (1) GENERAL PUBLIC WEBSITE FOR MORE INFORMATION ABOUT ANTHRAX (HTTP://WWW.ANTHRAX.OSD.MIL/)
- (2) OASD PA PRESS RELEASE
- (HTTP://WWW.DEFENSELINK.MIL/NEWS/JUN2002/B06282002\_BT338-02.HTML)
- (3) AFIS NEWS ARTICLE
- (HTTP://WWW.DEFENSELINK.MIL/NEWS/JUN2002/N06282002 200206283.HTML)
- (4) NAVY & MARINE CORPS MEDICAL NEWS
- (HTTP://NAVYMEDICINE.MED.NAVY.MIL/MEDNEWS/)
- (5) SPECIAL BRIEFING ON THE ANTHRAX VACCINE PROGRAM
- (HTTP://WWW.DEFENSELINK.MIL/NEWS/JUN2002/T06292002 T0628WW.HTML)
- B. PUBLIC AFFAIRS OFFICES CAN OBTAIN THE LATEST PUBLIC AFFAIRS GUIDANCE BY ACCESSING THE SECURE BUMED PUBLIC AFFAIRS WEBSITE (HTTPS://BUMED.MED.NAVY.MIL/ANTHRAXINFO.HTM)
- C. INSTALLATION AND OPERATIONAL COMMANDS WILL NORMALLY RESPOND TO LOCAL MEDIA QUERIES. HQMC PA SHOULD BE CONSULTED ON MEDIA QUERIES THAT MAY GARNER NATIONAL INTEREST.
- 9. HQMC POCS FOR THIS MESSAGE ARE: LTCOL TOM MCGINNIS OR MR DENNIS MORELAND, PPO, (703) 695-0221/0186 (DSN 225); CAPT KEN SCHOR (USN), HQMC PREVENTIVE MEDICINE OFFICER, (703) 614-4478 (DSN 224); CDR READING OR HMC LEPE, I&L (LPC-4), (703) 695-8926 (DSN 225); LCDR CELIA QUIVERS, CNO N931,

(703) 601-1716; CAPT STU UPTON, HQMC PUBLIC AFFAIRS, (703) 614-4309 (DSN 224). 9. EXPIRATION DATE CANNOT BE DETERMINED.//