ALARACT 032/2008

Subject: ALARACT 032/2008 DOD'S TRANSITION TO ACAM2000 BRAND OF SMALLPOX VACCINE (UNCLASSIFIED)

DTG:141607ZFeb08 Precedence: IMMEDIATE DAC: General To: AL ALARACT(UC), ALARACT UNCLASSIFIED//

THIS MESSAGE HAS BEEN SENT BY THE PENTAGON TELECOMMUNICATIONS CENTER ON BEHALF OF DA WASHINGTON DC//DASG//
THIS ALARACT MESSAGE IS BEING SENT OUT ON BEHALF OF THE SURGEON GENERAL//

SUBJECT: DOD'S TRANSITION TO ACAM2000 BRAND OF SMALLPOX VACCINE

REF/A/DOC/DEPSECDEF/30SEP02/APMN/DEPSECDEF MEMO/DEPARTMENT OF DEFENSE SMALLPOX RESPONSE PLAN//
REF/B/DOC/USD(P&R)/l3DEC02/APMN/USD(P&R) MEMO/POLICY ON ADMINISTRATIVE ISSUES RELATED TO SMALLPOX VACCINATION PROGRAM (SVP)//
REF/C/DOC/VCSA/I0JAN03/APMN/VCSA MEMO/ARMY SMALLPOX VACCINATION PROGRAM IMPLEMENTATION PLAN//
REF/D/MSG/HQDA//APMN/HQDA MSG/ARMY AUTHORIZATION TO PROCEED WITH SMALLPOX VACCINATION PROGRAM (SVP) FOR ARMY CIVILIAN EMPLOYEES//
REF/E/MSG/HQDA/171854ZJUL04/APMN/ALARACT(U) EXPANSION OF ANTHRAX AND SMALLPOX VACCINATION PROGRAMS//

1. (U) THE DEPARTMENT OF DEFENSE (DOD) IS TRANSITIONING FROM WYETH'S DRYVAX BRAND OF SMALLPOX VACCINE TO ACAMBIS' ACAM2000 BRAND OF SMALLPOX VACCINE. THE FOOD AND DRUG ADMINISTRATION (FDA) APPROVED LICENSURE OF ACAM2000 ON 31 AUG 07. SUBSEQUENTLY WYETH (THE MANUFACTURER OF DRYVAX) ANNOUNCED ITS PLAN TO WITHDRAW LICENSURE OF DRYVAX VACCINE.

2. (U) AT THIS TIME, ARMY COMMANDS (ACOM), ARMY SERVICE COMMANDS (ASCC) AND DIRECT REPORTING UNITS (DRU) ARE DIRECTED TO BEGIN USING ACAM2000 SMALLPOX VACCINE TO VACCINATE PERSONNEL AT RISK FROM THE VARIOLA VIRUS
NLT 29 FEB 08.

3. (U) EXECUTION.
3.A. (U) THE DOD POLICY FOR THE SMALLPOX VACCINATION PROGRAM (SVP) REMAINS UNCHANGED. THIS TRANSITION TO A NEW VACCINE DOES NOT CHANGE THE POPULATION BEING VACCINATED OR THE PREVIOUS REQUIREMENTS OF THE SVP.
3.A.(I) (U) SMALLPOX VACCINATION IS MANDATORY FOR UNIFORMED PERSONNEL AND ALL EMERGENCY ESSENTIAL AND EQUIVALENT CIVILIAN PERSONNEL ASSIGNED TO CENTCOM AOR OR TO THE KOREAN PENINSULA FOR 15 OR MORE CONSECUTIVE DAYS.
3.A.(2) (U) THE VACCINE WILL BE OFFERED TO FAMILY MEMBERS 18-65 YEARS OF AGE ACCOMPANYING DOD MILITARY AND CIVILIAN PERSONNEL FOR 15 OR MORE CONSECUTIVE DAYS TO THE CENTCOM AOR OR KOREAN PENINSULA
3.B. (U) ADMINISTRATION AND LOGISTICS TIMELINES
3.B.(I) (U) 30 JAN 08 ALL DRYVAX VACCINE AT HIGH VOLUME SITES WAS REPLACED WITH ACAM2000.
3.B.(2) (U) 29 FEB 08 IS THE DATE THAT DOD CLINICS SHOULD QUARANTINE ALL DRYVAX SMALLPOX VACCINE, DILUENT, AND NEEDLES. ACTIVITIES WILL CONTINUE THEIR SMALLPOX VACCINATION PROGRAMS WITH ACAM2000 VACCINE DO NOT USE DRYVAX SMALLPOX VACCINE AFTER 29 FEB 08.

3.B.(3) (U) 31 MAR 08 IS THE SUSPENSE DATE FOR ALL DOD DRYVAX SMALLPOX VACCINE, DILUENT, AND NEEDLES TO BE DESTROYED. DURING THE MONTH OF MARCH. DESTRUCTION PAPERWORK MUST BE FORWARDED TO US ARMY MEDICAL MATERIEL AGENCY'S (USAMMA) DISTRIBUTION OPERATIONS CENTER (DOC) DESTRUCTION INSTRUCTIONS ARE FORTHCOMING VIA A MEDICAL MATERIEL QUALITY CONTROL MESSAGE (MMQC) AND BY MONITORING THE MILITARY VACCINE (MILVAX) AGENCY WEBSITE WWW.VACCINES.MIL OR USAMMA'S WEBSITE WWW.USAMMA.ARMY.MIL.
3.B.(4) (U) 01 APR 08, ACAM2000 WILL BE FULLY IMPLEMENTED AS DOD'S SMALLPOX VACCINE.

4. (U) ADMINISTRATION AND LOGISTICS
4.A. (U) CLINICAL.
4.A.(1) (U) ACAM2000 IS ADMINISTERED SIMILAR TO DRYVAX VACCINE BY PERCUTANEOUS ROUTE (SCARIFICATION) USING A BIFURCATED NEEDLE LIKE DRYVAX VACCINE. ACAM2000 SHOULD NOT BE ADMINISTERED BY THE INTRADERMAL, SUBCUTANEOUS, INTRAMUSCULAR, OR INTRAVENOUS ROUTE
4.A.(2) (U) AFTER PROPER SCREENING, ALL PERSONNEL RECEIVING ACAM2000 (PRIMARY VACCINEES AND RE-VACCINEES) WILL RECEIVE 15 JABS WITH A BIFURCATED NEEDLE. PERSONNEL HANDLING OR ADMINISTERING ACAM2000 SHOULD WEAR GLOVES AND CHANGE THEM BETWEEN EVERY VACCINE RECIPIENT.
4.A.(3) (U) ACAM2000 WAS EVALUATED AGAINST DRYVAX SMALLPOX VACCINE IN SIX PRELICENSURE CLINICAL STUDIES AND FOUND TO HAVE A COMPARABLE SIDE-EFFECT PROFILE. THE MOST COMMON SIDE-EFFECTS FOLLOWING VACCINATION WITH ACAM2000 INCLUDE ITCHING, SWOLLEN LYMPH NODES, SORE ARM FEVER HEADACHE. BODY ACHE, MILD RASH AND FATIGUE. THERE WAS NO STATISTICAL DIFFERENCE IN THE INCIDENCE OF SERIOUS ADVERSE EVENTS (E G MYO/PERICARDITIS) BETWEEN ACAM2000 AND DRYVAX. THE PRELICENSURE ANALYSIS OF ACAM2000 PROVIDED SUFFICIENT DATA FOR THE FDA TO APPROVE IT FOR ACTIVE IMMUNIZATION AGAINST SMALLPOX DISEASE.
4.B. (U) EDUCATION REQUIREMENTS. PRIOR TO VACCINATION WITH ACAM2000 ALL VACCINEES MUST RECEIVE A COPY OF THE FDA APPROVED MEDICATION GUIDE AND THE DOD SMALLPOX INDIVIDUAL INFORMATION TRIFOLD BROCHURE. THESE TWO DOCUMENTS ARE SHIPPED TO CLINICS AT NO COST IN THE SAME QUANTITY AS ORDERED VACCINE. THE MEDICATION GUIDE WILL ALSO BE AVAILABLE ON A CD THAT WILL BE DISTRIBUTED WITH THE VACCINE. ADDITIONALLY, CLINICS MAY REQUEST ADDITIONAL COPIES THROUGH THE MILVAX BY PHONE 877-GET-VACC OR EMAIL VACCINES@AMEDD.ARMY.MIL. THESE PRODUCTS ARE ALSO AVAILABLE ONLINE FOR DOWNLOADING AT MILVAX WEBSITES WWW.VACCINES. MIL) ACAM2000 OR WWW.SMALLPOX.MIL, AND USAMMA WEBSITE WWW.USAMMA.ARMY.MIL/VACCINES/SMALLPOX.
4.C. (U) IMMUNIZATION RECORD KEEPING PROCEDURES. THERE IS NO CHANGE TO THE IMMUNIZATION RECORD KEEPING REQUIREMENTS. EVERY VACCINATION MUST BE ENTERED INTO A DOD APPROVED ELECTRONIC IMMUNIZATION TRACKING SYSTEM.
4.D. (U) NSN: 6505-01-559-0815, SMALLPOX (VACCINIA) VACCINE, LIVE WITH DILUENT, SYRINGES, AND NEEDLES.
4.E. (U) DOD USES THE SAME FDA APPROVED VACCINE THAT IS MAINTAINED IN THE STRATEGIC NATIONAL STOCKPILE. THEREFORE ALL DOD STOCK WILL HAVE THE "STRATEGIC NATIONAL STOCKPILE USE ONLY" PRINTED ON ITS LABEL THIS VACCINE IS APPROVED FOR USE IN THE DOD.
4.F. (U) THE USAMMA (DOC) WILL CONTINUE TO COORDINATE THE ALLOCATION AND THE DISTRIBUTION OF THE SMALLPOX VACCINE WITH THE MILVAX AGENCY.
4.G. (U) THE SMALLPOX VACCINE IS CENTRALLY FUNDED BY THE PROGRAM EXECUTIVE OFFICE FOR CHEMICAL BIOLOGICAL DEFENSE (PEOCBD) THE VACCINE IS NOT A DEFENSE SUPPLY CENTER PHILADELPHIA (DSCP), STOCKED ITEM-THEREFORE REQUISITIONS FOR THE VACCINE WILL BE SUBMITTED OFFLINE TO USAMMA DOC AT HTTP://WWW.USAMMA.ARMY.MIL.

5. (U) COMMAND AND CONTROL.
5.A. (U) COMMAND RELATIONSHIPS. COMMAND AND CONTROL RELATIONSHIPS REMAIN UNCHANGED UNDER THIS IMPLEMENTATION PLAN.
5.B. (U) COMMAND, CONTROL. COMMUNICATIONS AND COMPUTER SYSTEMS (C4)
5.B.(1) (U) DOCUMENTATION. ALL INDIVIDUAL IMMUNIZATIONS INCLUDING CIVILIAN EMPLOYEES AND CONTRACT PERSONNEL, WILL BE IMMEDIATELY POSTED AND TRACKED IN THE MEDICAL PROTECTION SYSTEM (MEDPROS), THE HQDA STANDARD FOR TRACKING ALL INDIVIDUAL MEDICAL READINESS INDICATORS IN THE ACTIVE AND RESERVE COMPONENTS. LEADERS AT ALL LEVELS CAN TRACK INDIVIDUAL AND UNIT COMPLIANCE USING MEDPROS. A MODERN, EASY TO USE, WEB-BASED TRACKING SYSTEM. ACCESSED ON THE INTERNET AT WWW.MODS.ARMY.MIL. USERS MAY OBTAIN INFORMATION ON HOW TO OBTAIN A LOGON ID DIRECTLY FROM THE WEBSITE OR BY CALLING THE MEDICAL OPERATIONAL DATA SYSTEM (MODS) HELP DESK DSN-761 4976, OR E-MAIL MODS-HELP@ASMR.COM FOR ASSISTANCE. COMMANDERS WILL ASSIGN DESIGNATED PERSONNEL TO ROUTINELY ACCESS MEDPROS TO KEEP THEIR UNITS STATUS CURRENT.
5.B.(2) (U) CIVILIAN EMPLOYEES AND CONTRACT PERSONNEL SHOULD BE GIVEN A COPY OF THEIR MEDPROS IMMUNIZATION RECORD (DD FORM 2766C) BY THE MEDICAL TREATMENT FACILITY (MTF) WHERE THEY ARE IMMUNIZED AND/OR WHERE THEIR IMMUNIZATION INFORMATION IS ENTERED INTO MEDPROS
5.C. (U) HQDA POCS: COL RANDALL ANDERSON OR LTC PATRICK GARMAN. COM 703-681-5101. DSN: 761-5101. EMAIL: VACCINES@AMEDD.ARMY.MIL, OR VACCINES@HQDA-S.ARMY.SMIL.MIL (ATTENTION: MILVAX).

6. (U) EXPIRATION DATE CANNOT BE DETERMINED,