

***** UNCLASSIFIED // *****

Subject: ALARACT 268/2011 - IMPLEMENTATION OF ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE

Originator: /C=US/O=U.S.

GOVERNMENT/OU=DOD/OU=ARMY/OU=ORGANIZATIONS/L=CONUS/L=WASHINGTON DC/OU=DA PENTAGON TELECOMMUNICATIONS(UC)/OU=ALARACT RELEASE AUTHORITY(UC)

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Precedence: PRIORITY

DAC: General

To: /C=US/O=U.S. GOVERNMENT/OU=DOD/OU=AUTODIN PLAS/OU=AIG

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THIS MESSAGE HAS BEEN SENT BY THE PENTAGON TELECOMMUNICATIONS CENTER ON BEHALF OF DA WASHINGTON DC//DASG-HSZ/DAMO-DASG//

THIS ALARACT MESSAGE IS SENT ON BEHALF OF THE SURGEON GENERAL//

SUBJECT: IMPLEMENTATION OF ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE

REF/A/REG/HQDA/ARMY REGULATION 40-562/IMMUNIZATIONS AND CHEMOPROPHYLAXIS/20SEP06// REF/B/BARR LABS, INC. MANUFACTURERS PACKAGE INSERT// REF/C/CENTERS FOR DISEASE CONTROL AND PREVENTION/VACCINE INFORMATION STATEMENT (VIS)/ADENOVIRUS VACCINE/14JUL11//

1. (U) SITUATION: ON 16 MAR 11, THE FOOD AND DRUG ADMINISTRATION (FDA) LICENSED THE ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE, MANUFACTURED BY TEVA PHARMACEUTICALS USA/BARR LABORATORIES, FOR USE IN MILITARY POPULATIONS 17 TO 50-YEARS OF AGE. THIS MESSAGE PROVIDES GUIDANCE ON HOW TO ADMINISTER ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE AMONG INITIAL ENTRY TRAINING (IET) SOLDIERS AT ARMY BASIC COMBAT TRAINING CENTERS. ADENOVIRUS TYPES 4 AND 7 VACCINE PROTECTS THE INDIVIDUAL VACCINATED FROM ACUTE RESPIRATORY DISEASE CAUSED BY ADENOVIRUS TYPES 4 AND 7.

2. (U) MISSION. (SEC)ARMY DIRECTS US ARMY MEDICAL COMMAND (USAMEDCOM), IN COORDINATION WITH TRAINING AND DOCTRINE (TRADOC) AND INSTALLATION MANAGEMENT COMMAND (IMCOM), TO ADMINISTER ADENOVIRUS TYPES 4 AND 7 VACCINE WHEN AVAILABLE AT US ARMY BASIC COMBAT TRAINING CENTERS TO INCOMING IET SOLDIERS BETWEEN 17 AND 50-YEARS OF AGE.

3. (U) EXECUTION.

3.A. (U) CLINICAL.

3.A.(1) (U) ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE IS A SINGLE DOSE ADMINISTERED AS TWO-ENTERIC COATED TABLETS: ONE TABLET OF ADENOVIRUS TYPE 4 (WHITE TAB) AND ONE TABLET OF ADENOVIRUS TYPE 7 (LIGHT PEACH TAB).

3.A.(2) (U) ADENOVIRUS VACCINE TYPES 4 AND 7 CAN BE ADMINISTERED SIMULTANEOUSLY OR AT ANY INTERVAL BEFORE OR AFTER OTHER VACCINES, INCLUDING LIVE VACCINES.

3.A.(3) (U) THE ADENOVIRUS VACCINE IS ADMINISTERED ONLY ONCE, AT IET AND BOOSTERS ARE NOT REQUIRED.

3.A.(4) (U) TABLETS MUST BE SWALLOWED WHOLE, NOT CHEWED OR CRUSHED TO AVOID RELEASING THE LIVE ADENOVIRUS IN THE UPPER RESPIRATORY TRACT.

3.A.(5) (U) EACH VACCINE ADMINISTRATION WILL BE DIRECTLY OBSERVED TO VERIFY TABLETS ARE SWALLOWED.

3.B. (U) CONTRAINDICATIONS.

3.B.(1) (U) DO NOT ADMINISTER ADENOVIRUS VACCINE TO PREGNANT FEMALES.

3.B.(2) (U) DO NOT ADMINISTER TO INDIVIDUALS WHO DEVELOPED A SEVERE ALLERGIC REACTION AFTER PREVIOUS RECEIPT OF ANY COMPONENT OF THE VACCINE AND/OR THOSE WHO HAVE A SENSITIVITY TO FD&C YELLOW #6-ALUMINUM LAKE DYE.

3.B.(3) (U) DO NOT ADMINISTER TO INDIVIDUALS WHO ARE INCAPABLE OF SWALLOWING THE TABLETS WHOLE WITHOUT CHEWING.

3.B.(4) (U) POSTPONE VACCINE ADMINISTRATION TO INDIVIDUALS WITH VOMITING AND/OR DIARRHEA.

3.C. (U) WARNINGS/PRECAUTIONS.

3.C.(1) (U) WOMEN SHOULD NOT BECOME PREGNANT FOR AT LEAST 6-WEEKS AFTER RECEIVING THE VACCINE.

3.C.(2) (U) ADENOVIRUS VACCINE CONTAINS LIVE ADENOVIRUS THAT IS SHED IN THE STOOL FOR UP TO 28-DAYS FOLLOWING VACCINATION. STRICT HANDWASHING AND PERSONAL HYGIENE IS REQUIRED TO MINIMIZE RISK OF TRANSMITTING THE VIRUS TO OTHERS.

3.C.(3) (U) VACCINEES SHOULD PAY CLOSE ATTENTION TO PERSONAL HYGIENE WHEN AROUND CHILDREN SEVEN-YEARS OF AGE AND YOUNGER, IMMUNOCOMPROMISED INDIVIDUALS, AND PREGNANT WOMEN FOR 28-DAYS FOLLOWING VACCINATION.

3.C.(4) (U) REPORT ADVERSE EVENTS AFTER IMMUNIZATION TO THE VACCINE ADVERSE EVENT REPORTING SYSTEM, WWW.VAERS.HHS.GOV.

3.D. (U) EDUCATION.

3.D.(1) (U) GENERAL. DETAILED CLINICAL AND BASIC INFORMATION ABOUT THE ADENOVIRUS VACCINE IS AVAILABLE AT WWW.VACCINES.MIL/ADENOVIRUS OR WWW.CDC.GOV/VACCINES/PUBS/VIS/DEFAULT.HTM.

3.D.(2) ((U) FEMALE PERSONNEL WHO RECEIVED THE VACCINE DURING PREGNANCY OR BECAME PREGNANT WITHIN SIX-WEEKS OF VACCINATION SHOULD BE PROVIDED INFORMATION ABOUT THE ADENOVIRUS VACCINE PREGNANCY REGISTRY FOR SELF REFERRAL. PER THE PACKAGE INSERT, ALL CASES IN WHICH A WOMEN RECEIVES ADENOVIRUS TYPE 4 AND TYPE 7 VACCINE, LIVE, ORAL DURING PREGNANCY OR

BECOMES PREGNANT (CONCEPTION OCCURS) WITHIN SIX-WEEKS FOLLOWING VACCINATION SHOULD BE REPORTED TO THE ADENOVIRUS PREGNANCY REGISTRY BY CALLING COM: 1-866-790-4549.

3.D.(3) (U) HANDOUTS. THE CENTERS FOR DISEASE CONTROL & PREVENTION (CDC) ISSUED A VACCINE INFORMATION STATEMENT (VIS) FOR ADENOVIRUS. THIS VIS IS THE ARMY STANDARD FOR PATIENT-LEVEL INFORMATION ABOUT ADENOVIRUS VACCINE AND IS AVAILABLE AT WWW.VACCINES.MIL/ADENOVIRUS.

3.D.(4) (U) PROVIDE ALL VACCINEES EDUCATIONAL MATERIALS AND THE OPPORTUNITY TO READ THE VIS (POSTER OR VIS HANDOUT).

3.E. (U) DOCUMENTATION. ALL IMMUNIZATIONS GIVEN TO MILITARY PERSONNEL WILL BE IMMEDIATELY RECORDED IN THE MEDICAL PROTECTION SYSTEM (MEDPROS).

3.E.(1) (U) THE MEDPROS CODE FOR ADENOVIRUS TYPES 4 AND 7 VACCINE IS "143".

3.E.(2) (U) USERS MAY REQUEST A LOGON ID DIRECTLY FROM THE WEBSITE (WWW.MODS.ARMY.MIL) OR BY CALLING THE MODS HELP DESK, COM: 1-888-849-4341, DSN: 761-4976.

4. (U) ADMINISTRATION/LOGISTICS.

4.A. (U) THE US ARMY MEDICAL MATERIEL AGENCY (USAMMA) WILL COORDINATE THE DISTRIBUTION OF THE ADENOVIRUS VACCINE TO THE SUPPORTING MEDICAL SUPPLY ACTIVITIES OF ALL SERVICES. LOCAL MEDICAL LOGISTICS SUPPORTING ELEMENTS MUST HAVE SUFFICIENT REFRIGERATION CAPACITY TO PRESERVE VACCINE INTEGRITY, INCLUDING TEMPERATURE ALARMS AND BACK UP POWER CAPACITY.

4.B. (U) USAMMA POCS:

4.B.(1) (U) USAMMA DISTRIBUTION OPERATIONS CENTER, COM: 301-619-4318/1197/4198, DSN: 343-4318/1197/4198, FAX: DSN: 343-4468.

4.B.(2) (U) WEBSITE: WWW.USAMMA.ARMY.MIL.

4.C. (U) THE MANUFACTURER WILL SHIP THE ADENOVIRUS VACCINE DIRECTLY TO THOSE INSTALLATIONS THAT RECEIVE AND PROCESS NEW IET SOLDIERS. USAMMA DISTRIBUTION OPERATIONS CENTER WILL COORDINATE WITH ALL APPROPRIATE INSTALLATION MEDICAL SUPPLY ACTIVITIES WHEN THE DOD IS READY TO COMMENCE SHIPMENT OF VACCINE.

4.D. (U) COMMAND.

4.D.(1) (U) USAMEDCOM IS THE LEAD.

4.D.(2) (U) SUPPORTED COMMANDS. TRADOC AND IMCOM.

5. (U) COORDINATING INSTRUCTIONS:

5.A. (U) POCS:

5.A.(1) (U) MS. TRACI VACTOR, COM: 703-325-6538, DSN: 221-6538, EMAIL: TRACI.VACTOR@US.ARMY.MIL.

5.A.(2) (U) LTC PATRICK GARMAN, COM: 703-325-6548, DSN: 221-6548, EMAIL: PATRICK.GARMAN@US.ARMY.MIL.

5.A.(3) (U) HQDA AOC: SURGEON ACTION OFFICER, COM: 703-693-4821, DSN: 223-4821, EMAIL: OTSG.AOCCAT@CONUS.ARMY.MIL.

- 5.B. (U) ACKNOWLEDGE RECEIPT BY EMAIL TO POC IN PARA 5.A.(3).
- 5.C. (U) EXPIRATION DATE: 15 MAR 16.