FROM

QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

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**********UNCLASSIFIED**********

SUBJ: MMQC-12-1016

FDA APPROVES A CLASS RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES / FDA MEDWATCH

01. EXCERPT FROM FDA MEDWATCH.

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVED A SINGLE, SHARED SYSTEM RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR THE ENTIRE CLASS OF TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) PRESCRIPTION MEDICINES. THIS REMS, CALLED THE TIRF REMS ACCESS PROGRAM, CONSISTS OF A RESTRICTED DISTRIBUTION PROGRAM TO REDUCE THE RISK OF MISUSE, ABUSE, ADDICTION, AND OVERDOSE WITH TIRF MEDICINES.

THE TIRF REMS ACCESS PROGRAM IS THE FIRST APPROVED CLASS REMS FOR DRUGS IN THE OPIOID CLASS. WE ARE CONTINUING WORK ON ANOTHER CLASS REMS FOR THE CLASS OF LONG-ACTING AND EXTENDED-RELEASE OPIOIDS.

THE FOLLOWING QUESTIONS AND ANSWERS PROVIDE AN OVERVIEW OF THE NEW SHARED REMS FOR TIRF MEDICINES.

Q1. WHAT ARE TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES?

Q2. WHAT IS A RISK EVALUATION AND MITIGATION STRATEGY (REMS)?

Q3. WHY DID FDA APPROVE A SHARED, SINGLE-SYSTEM RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR THE ENTIRE CLASS OF TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL

(TIRF) MEDICINES, WHEN THE TIRF MEDICINES ALREADY HAD INDIVIDUAL REMS IN PLACE?

Q4. DOES THIS NEW RISK EVALUATION AND MITIGATION STRATEGY (REMS) APPLY TO ALL OPIOIDS?

Q5. WILL THIS ACTION MAKE IT HARDER FOR PATIENTS TO RECEIVE THEIR TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES?

Q6. WHAT SHOULD PRESCRIBERS KNOW ABOUT THE NEW SHARED TIRF REMS ACCESS PROGRAM?

Q7. WHAT SHOULD PHARMACIES/PHARMACISTS KNOW ABOUT THE NEW SHARED TIRF REMS ACCESS PROGRAM?

Q8. WHAT SHOULD PATIENTS KNOW ABOUT THE NEW SHARED TIRF REMS ACCESS PROGRAM?

Q9. WHEN DOES THE TIRF REMS ACCESS PROGRAM “GO LIVE” OR BECOME FULLY OPERATIONAL?

WHAT DO PATIENTS ON TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES DO IN THE INTERIM?

Q1. WHAT ARE TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES?

A. TIRF MEDICINES CONTAIN FENTANYL, A PRESCRIPTION OPIOID (NARCOTIC) PAIN RELIEVER.

TIRF MEDICINES ARE USED TO MANAGE BREAKTHROUGH PAIN IN ADULTS WITH CANCER WHO ARE ROUTINELY TAKING OTHER OPIOID PAIN MEDICINES AROUND-THE-CLOCK FOR PAIN.

BREAKTHROUGH PAIN IS PAIN THAT COMES ON SUDDENLY FOR SHORT PERIODS OF TIME AND IS NOT ALLEVIATED BY A PATIENT’S NORMAL PAIN MANAGEMENT PLAN. TO USE THE TIRF MEDICINES SAFELY,

THESE PATIENTS MUST BE OPIOID TOLERANT BASED ON CONCURRENT REGULAR USE OF ANOTHER OPIOID MEDICATION.

THE CURRENT LIST OF TIRF MEDICINES INCLUDE ABSTRAL (FENTANYL) SUBLINGUAL TABLET, ACTIQ (FENTANYL CITRATE) ORAL TRANSMUCOSAL LOZENGE AND ITS GENERIC EQUIVALENTS, FENTORA (FENTANYL CITRATE) BUCCAL TABLET, LAZANDA (FENTANYL) NASAL SPRAY, AND ONSOLIS (FENTANYL) BUCCAL.

Q2. WHAT IS A RISK EVALUATION AND MITIGATION STRATEGY (REMS)?

A. A REMS IS A RISK MANAGEMENT PLAN THAT USES RISK MINIMIZATION STRATEGIES BEYOND APPROVED LABELING TO MANAGE SERIOUS RISKS ASSOCIATED WITH A DRUG. UNDER THE FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007, FDA HAS THE AUTHORITY TO REQUIRE A MANUFACTURER TO DEVELOP A REMS WHEN FDA FINDS A REMS IS NECESSARY TO ENSURE THAT THE BENEFITS OF A DRUG OUTWEIGH ITS RISKS.

A REMS CAN INCLUDE A MEDICATION GUIDE OR PATIENT PACKAGE INSERT, COMMUNICATION PLAN, ONE OR MORE ELEMENTS TO ASSURE SAFE USE, AN IMPLEMENTATION SYSTEM, AND A TIMETABLE FOR SUBMISSION OF THE REMS ASSESSMENTS.

Q3. WHY DID FDA APPROVE A SHARED, SINGLE-SYSTEM RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR THE ENTIRE CLASS OF TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL

(TIRF) MEDICINES, WHEN THE TIRF MEDICINES ALREADY HAD INDIVIDUAL REMS IN PLACE?

A. FDA APPROVED A SHARED, SINGLE-SYSTEM REMS FOR TIRF MEDICINES TO REDUCE THE BURDEN ON THE HEALTHCARE SYSTEM OF HAVING SEPARATE REMS PROGRAMS IN PLACE FOR INDIVIDUAL TIRF MEDICINES. UNDER THE NEW CLASS REMS, PRESCRIBERS, PHARMACIES, DISTRIBUTORS, AND OUTPATIENTS WILL ONLY NEED TO ENROLL IN ONE REMS PROGRAM

- THE TIRF REMS ACCESS PROGRAM - TO PRESCRIBE, DISPENSE, OR RECEIVE ALL DRUGS IN THE TIRF MEDICINES CLASS.

Q4. DOES THIS NEW RISK EVALUATION AND MITIGATION STRATEGY (REMS) APPLY TO ALL OPIOIDS?

A. NO. THIS REMS IS APPROVED SPECIFICALLY FOR TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES. THIS REMS WILL NOT AFFECT THE PRESCRIBING AND USE OF OTHER OPIOIDS. WE ARE CONTINUING WORK ON ANOTHER CLASS REMS FOR THE CLASS OF LONG-ACTING AND EXTENDED-RELEASE OPIOIDS.

Q5. WILL THIS ACTION MAKE IT HARDER FOR PATIENTS TO RECEIVE THEIR TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES?

A. NO. FDA DOES NOT EXPECT THAT THIS NEW CLASS RISK EVALUATION AND MITIGATION STRATEGY (REMS) WILL AFFECT PATIENT ACCESS TO TIRF MEDICINES COMPARED TO THE INDIVIDUAL REMS. HAVING A SINGLE SHARED REMS FOR ALL OF THE TIRF MEDICINES WILL MAKE IT EASIER FOR PRESCRIBERS AND PHARMACIES TO PARTICIPATE IN THE TIRF REMS ACCESS PROGRAM, WHICH WE EXPECT TO IMPROVE PATIENT ACCESS. SPONSORS WILL ALSO BE REQUIRED TO EVALUATE THE IMPACT OF THE REMS ON PATIENT ACCESS TO THEIR TIRF MEDICINES AS PART OF REQUIRED PERIODIC ASSESSMENTS OF THE REMS, AND FDA WILL REVIEW THESE ASSESSMENTS.

Q6. WHAT SHOULD PRESCRIBERS KNOW ABOUT THE NEW SHARED TIRF REMS ACCESS PROGRAM?

A. HEALTHCARE PROVIDERS WHO PRESCRIBE TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL

(TIRF) MEDICINES FOR OUTPATIENT USE ARE REQUIRED TO ENROLL IN THE TIRF REMS ACCESS PROGRAM. HEALTHCARE PROVIDERS WHO ARE ALREADY ENROLLED IN AN INDIVIDUAL RISK EVALUATION AND MITIGATION STRATEGY (REMS) PROGRAM FOR AT LEAST ONE TIRF MEDICINE WILL NOT NEED TO RE-ENROLL BECAUSE THEY WILL BE AUTOMATICALLY TRANSITIONED TO THE SHARED TIRF REMS ACCESS PROGRAM. PRESCRIBERS WILL BE REQUIRED TO RE-ENROLL IN THE TIRF REMS PROGRAM EVERY TWO YEARS FROM THE DATE OF ENROLLMENT INTO THE TIRF CLASS REMS OR FROM THE DATE OF ENROLLMENT INTO THE INDIVIDUAL REMS, WHICHEVER

WAS EARLIER.

TO ENROLL, PRESCRIBERS MUST REVIEW THE EDUCATION PROGRAM, SUCCESSFULLY COMPLETE THE KNOWLEDGE ASSESSMENT, AND COMPLETE AN ENROLLMENT FORM. ADDITIONAL INFORMATION ABOUT THE ENROLLMENT PROCESS CAN BE FOUND ON THE TIRF REMS ACCESS PROGRAM WEBSITE:

WWW.TIRFREMSACCESS.COM. THIS WEBSITE WILL BE AVAILABLE IN MARCH 2012 WHEN THE TIRF REMS ACCESS PROGRAM "GOES LIVE."

IN OUTPATIENT SETTINGS, ALL HEALTHCARE PROVIDERS MUST COMPLETE AND SIGN A TIRF REMS ACCESS PATIENT-PRESCRIBER AGREEMENT FORM WITH EACH NEW PATIENT BEFORE WRITING THE PATIENT'S FIRST TIRF PRESCRIPTION. HEALTHCARE PROVIDERS MUST ALSO PROVIDE PATIENTS WITH A COPY OF THE MEDICATION GUIDE DURING COUNSELING ABOUT THE PROPER USE OF THEIR TIRF MEDICINE.

HEALTHCARE PROVIDERS WHO PRESCRIBE TIRF MEDICINES FOR INPATIENT USE ONLY (E.G.

HOSPITALS, HOSPICES, OR LONG-TERM CARE FACILITIES) ARE NOT REQUIRED TO ENROLL IN THE TIRF REMS ACCESS PROGRAM.

Q7. WHAT SHOULD PHARMACIES/PHARMACISTS KNOW ABOUT THE NEW SHARED TIRF REMS ACCESS PROGRAM?

A. BOTH OUTPATIENT AND INPATIENT PHARMACIES THAT DISPENSE TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES ARE REQUIRED TO ENROLL IN THE TIRF REMS ACCESS PROGRAM. PHARMACIES THAT WERE PREVIOUSLY ENROLLED IN AN INDIVIDUAL TIRF RISK EVALUATION AND MITIGATION STRATEGY (REMS) WILL NOT NEED TO RE-ENROLL BECAUSE THEY WILL BE AUTOMATICALLY TRANSITIONED TO THE SHARED TIRF REMS ACCESS PROGRAM. PHARMACIES WILL BE REQUIRED TO RE-ENROLL IN THE TIRF REMS PROGRAM EVERY TWO YEARS FROM THE DATE OF ENROLLMENT INTO THE TIRF CLASS REMS OR FROM THE DATE OF ENROLLMENT INTO THE INDIVIDUAL REMS, WHICHEVER WAS EARLIER.

FOR PHARMACIES TO ENROLL, A DESIGNATED AUTHORIZED PHARMACIST MUST REVIEW THE EDUCATION PROGRAM, SUCCESSFULLY COMPLETE THE KNOWLEDGE ASSESSMENT, AND COMPLETE AN ENROLLMENT FORM. ONLY THEN CAN THE AUTHORIZED PHARMACIST COMPLETE ENROLLMENT ON BEHALF OF THE PHARMACY. THE AUTHORIZED PHARMACIST WILL THEN TRAIN OTHER PHARMACY STAFF IN THE APPROPRIATE DISPENSING OF TIRF MEDICINES ACCORDING TO THE TIRF REMS ACCESS PROGRAM. ADDITIONAL INFORMATION ABOUT THE ENROLLMENT PROCESS CAN BE FOUND ON THE TIRF REMS ACCESS PROGRAM WEBSITE: WWW.TIRFREMSACCESS.COM.

THIS WEBSITE WILL BE AVAILABLE IN MARCH 2012 WHEN THE TIRF REMS ACCESS PROGRAM "GOES LIVE."

Q8. WHAT SHOULD PATIENTS KNOW ABOUT THE NEW SHARED TIRF REMS ACCESS PROGRAM?

A. PATIENTS WHO ARE PRESCRIBED TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES ON AN OUTPATIENT BASIS MUST SIGN A PATIENT-PRESCRIBER AGREEMENT WITH THEIR HEALTHCARE PROVIDER AND WILL BE ASKED TO READ THE MEDICATION GUIDE PROVIDED TO THEM BY THEIR PRESCRIBER. PATIENTS CAN THEN TAKE THEIR PRESCRIPTION TO AN ENROLLED PHARMACY. PATIENTS CAN LOCATE A PARTICIPATING PHARMACY BY CONSULTING THEIR PRESCRIBER OR CALLING THE TIRF REMS ACCESS PROGRAM AT 1-866-822-1483.

THIS PHONE NUMBER WILL BE AVAILABLE IN MARCH 2012 WHEN THE TIRF REMS ACCESS PROGRAM "GOES LIVE." PATIENTS WILL BE ENROLLED IN THE TIRF REMS ACCESS PROGRAM BY THE PHARMACY AT THE TIME THEIR FIRST PRESCRIPTION IS FILLED.

PATIENTS WHO RECEIVE TIRF MEDICINES IN AN INPATIENT SETTING (E.G. HOSPITALS, HOSPICES, OR LONG-TERM CARE FACILITIES) ARE NOT REQUIRED TO PARTICIPATE IN THE TIRF REMS ACCESS PROGRAM.

Q9. WHEN DOES THE TIRF REMS ACCESS PROGRAM GO LIVE OR BECOME FULLY OPERATIONAL?

WHAT DO PATIENTS ON TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) MEDICINES DO IN THE INTERIM?

A. THE TIRF REMS ACCESS PROGRAM WILL "GO LIVE" IN MARCH 2012. UNTIL THIS TIME, PATIENTS PRESCRIBED TIRF MEDICINES WILL CONTINUE TO GET THEM THROUGH THE INDIVIDUAL RISK EVALUATION AND MITIGATION STRATEGIES (REMS) OR RISK MANAGEMENT PLAN PROGRAMS.

- CONTACT FDA

1-800-332-1088

1-800-FDA-0178 FAX

REPORT A SERIOUS PROBLEM

MEDWATCH ONLINE:

- COMPLETE AND SUBMIT THE REPORT ONLINE: WWW.FDA.GOV/MEDWATCH/REPORT.HTM <HTTP://WWW.FDA.GOV/MEDWATCH/REPORT.HTM>

REGULAR MAIL: USE POSTAGE-PAID FDA FORM 35006:

- DOWNLOAD FORM OR CALL 1-800-332-1088 TO REQUEST A REPORTING FORM, THEN COMPLETE AND RETURN TO THE ADDRESS ON THE PRE-ADDRESSED FORM OR SUBMIT BY FAX TO 1-800-FDA-0178.

02. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, PHARMACY, INTERNAL MEDICINE, CLINICAL STAFF, MED STAFF, CRITICAL CARE MEDICINE, EMERGENCY MEDICINE, RISK MANAGER, SUPPLY OFCRS, AND SUPPORTED ACTYS/CTRS.

03. AUTHORITY: DODD 5105.22 AND DODD 6025.13. ADDITIONALLY:

A. ARMY: SEE ARMY REGULATION (AR) 40-61, 28 JANUARY 2005, CHAPTER 4, AND THE DEPARTMENT OF THE ARMY SUPPLY BULLETIN (SB 8-75-11) FOR APPLICABLE POLICIES AND PROCEDURES.

B. AIR FORCE: AF ACTIVITIES WILL TAKE ACTION AS PRESCRIBED IN AFI 41-209, MEDICAL LOGISTICS SUPPORT, CHAPTERS 3 AND 9. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES.

04. SERVICE SPECIFIC POCS ARE AS FOLS (FAX NOS. ARE AVAILABLE 24 HRS);

ARMY: TELEPHONE COM: 301-619-4300, DSN: 343, FAX: 4468,

E-MAIL: QUADSERVICEMMQC@AMEDD.ARMY.MIL

ARMY MEMBERS MAY SUBSCRIBE TO DOD MMQC MESSAGES AND MANY OTHER TOPICS AT THE FOLLOWING WEBSITE:

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AIR FORCE: TELEPHONE COM: 301-619-4170, DSN: 343, FAX: 2557

EMAIL: AFMOA.SGALC@DETRICK.AF.MIL

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HTTPS://MEDLOG.DETRICK.AF.MIL/, GO TO "SITE SETTINGS" AND CHECK "SUBSCRIBE TO MMQC MESSAGES."

NAVY: TELEPHONE COM: 301-619-3085, DSN: 343, FAX: 3087,

EMAIL: MMQC2@MED.NAVY.MIL

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